In 8/4-C16/2

95th Congress
2d Session

COMMITTEE PRINT

COMMITTEE PRINT No. 95–67

CANCER-CAUSING CHEMICALS IN FOOD

REPORT

together with

SEPARATE VIEWS

BY THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

NINETY-FIFTH CONGRESS

SECOND SESSION

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DECEMBER 1978

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LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C., December 1978.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
Washington, D.C.

DEAR CHAIRMAN STAGGERS: The attached report by the Subcommittee on Oversight and Investigations reviews the Federal government's efforts to protect the public from potentially dangerous amounts of pesticide residues in food. It focuses on the activities of the Environmental Protection Agency (EPA), Department of Agriculture (USDA), and the Food and Drug Administration (FDA) with regard to pesticide tolerance setting, residue monitoring, and enforcement of statutes designed to keep unhealthy levels of pesticides from being deposited on or in food products.

The Subcommittee concludes that these programs are inadequate. As a result, American consumers cannot be sure that the meat, poultry, fruits, and vegetables they buy are not tainted with potentially dangerous pesticide residues.

We all have to eat. Because of the nature of chemical contaminants, we are forced to rely on the Federal government to protect us against potentially dangerous chemicals we cannot see, smell, or taste. Our examination leads us to believe that we cannot rely on the Federal government to protect us.

We found for instance that EPA (1) continues to approve tolerances for potentially carcinogenic, mutagenic, and teratogenic pesticides which result in residues in or on food; (2) has set tolerances for some of these pesticides without complete safety data; (3) has exempted some potentially dangerous pesticides from its tolerance requirements which end up in or on food; (4) uses an inadequate and outdated statistical base for setting tolerance levels; (5) often does not know what level of pesticide residue usually results from the use of a product; and (6) bases its approval of pesticides merely on industry-supplied safety data which often does not fully examine the potential hazard posed by the pesticide.

In sum, the Subcommittee concludes that EPA's tolerance setting program is abysmal and needs a complete overhaul.

Additionally, the Subcommittee is alarmed with the inadequate monitoring and enforcement programs of USDA and FDA. The Subcommittee found that even when meat was found to be contaminated with dangerously high levels of toxic pesticides neither USDA nor FDA could stop these products from reaching the dinner table. This is an appalling state of affairs which cannot be allowed to continue.

The Subcommittee recommends that these agencies move quickly to correct those deficient programs. The Subcommittee also suggests that Congress act to strengthen regulation of potentially dangerous pesticide products and direct these agencies to move vigorously to enforce the law.

The Subcommittee further recommends that if the agencies involved cannot or will not take appropriate action to protect the public, then Congress should consider legislation to place those responsibilities in the hands of an agency more concerned with protecting public health.

Sincerely,

JOHN E. MOSS,
Chairman.

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CANCER-CAUSING CHEMICALS IN FOOD

Chapter I.—Introduction and Methodology

On February 14, 16, and 24, 1978, the Subcommittee on Oversight and Investigations of the Interstate and Foreign Commerce Committee held hearings concerning cancer-causing chemicals in food. The hearings and concurrent Subcommittee investigation, which extended from October of 1977 through August of 1978, explored the shared responsibilities of the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA) in regulating toxic chemicals in food.

The hearings and investigation were part of a series of Subcommittee inquiries into the effectiveness of federal regulatory programs designed to reduce consumer exposure to cancer-causing substances. Over the past two and a half years the Subcommittee has examined problems associated with Nitrosamines,[1] Carbon Tetrachloride contamination of drinking water,[2] Polybrominated Biphenyls (PBB's),[3] chemicals in hair dyes and cosmetics[4] the use of the flame retardant, Tris, in children's sleepwear,[5] cigarettes,[6] and, most recently, the disposal of hazardous wastes.[7]

During the course of its investigation into environmental causes of cancer, the Subcommittee has examined federal statutes governing regulation of toxic chemicals that are administered by the Environmental Protection Agency (EPA), National Institute of Occupational Safety and Health (NIOSH), Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), Occupational Safety and Health Administration (OSHA), and Consumer Product Safety Commission (CPSC).

During its investigation into cancer-causing chemicals in food, the Subcommittee reviewed hundreds of EPA, FDA and USADA files, worked closely with the General Accounting Office (GAO) to assess federal programs designed to regulate toxic substances in food, and reviewed all relevant federal statutes and regulations.

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[1] "Environmental Causes of Cancer," hearings before the Subcommittee on Oversight and Investigations Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 94th Cong., 2d sess., ser No. 94–141.

[2] "Carbon Tetrachloride Contamination of Public Drinking Water," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 1st sess., ser. No. 95–29.

[3] "Adverse Effects of Polybrominated Biphenyls (PBB's)," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 1st sess. ser. No. 95–65.

[4] "Cancer-Causing Chemicals—Part I: Safety of Cosmetics and Hair Dyes," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong. 2d sess., ser. No. 95–91.

[5] "Regulation of Cancer-Causing Flame-Retardant Chemicals and Governmental Coordination of Testing of Toxic Chemicals (Tris)," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 1st sess., ser. No. 95–33.

[6] "Cigarette Smoking and Health," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 2d sess., Oct. 5 and 6, 1978.

[7] "Federal Implementation of the Resource Conservation and Recovery Act," hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 2d sess. Oct. 30, 1978.

The Subcommittee learned that, despite federal programs designed to protect the public from harmful chemicals, virtually all food consumed in this country contains residues of synthetic substances that have been developed in recent decades. Scores of these chemicals have lately been linked to cancer, birth defects and permanent genetic mutations. Still others have never been tested for safety.

Pesticides are a ubiquitous source of chemical residues in food. Two hundred seventy-one pesticides are registered for agricultural use in the United States. Forty-one cancer, genetic mutations, birth defects and/or reproductive disorders. Another 92 lack safety studies for these serious injurious effects. Yet, they continue to be sold and widely used under the direction of federal regulatory programs.

The Subcommittee's hearings and investigation focused on pesticides and two other groups of chemicals that are detected as residues in food during government monitoring:

1. Pesticides (literally "pest killers") include herbicides (weed killers), fungicides (mold, mushroom, mildew, and rust destroyers and repellants) and insecticides (insect killers). Modern agriculture depends on the use of pesticides. Unfortunately, pesticides, which routinely remain as residues in finished produce, are often toxic to animals and humans as well as to the pests they are formulated to destroy. Residues of pesticides are consistently found in samples of human blood, urine and milk.

2. Animal drugs, such as antibiotics and sulfa drugs, are routinely administered to livestock to prevent the spread of disease and, in some cases, to promote growth. Animal drugs are the most frequently detected chemical contaminants in meat and poultry. This report explains ways in which animal drugs are carelessly and intentionally abused. While the effects of these drugs on human health have not been well researched, the report explores their known and suspected hazards.

3. Industrial contaminants can adulterate food although they are not applied directly on crops or fed to livestock. For example, industrial pollution of water can result in contaminated fish.

Chapter II is a discussion of the Environmental Protection Agency, which is entrusted with the responsibility of approving pesticides for use. Under the terms of the Federal Food, Drug, and Cosmetic Act (FFDCA), the EPA establishes pesticide tolerances for raw agricultural commodities (maximum amounts of active pesticide ingredients that may be legally present in or on particular foods and animal feeds). Tolerance-setting under the FFDCA is a prerequisite of pesticide registration—or licensing for use—under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The pesticide registration system is also in EPA's jurisdiction. EPA has the authority to prosecute violators of pesticide use laws.

Chapter III is a discussion of the U.S. Department of Agriculture's regulatory responsibilities concerning chemical residues in food. USDA conducts two residue monitoring programs for toxic substances in edible animal tissues. USDA's *random sample* monitoring program analyzes tissue samples from a percentage of randomly selected animal carcasses in slaughterhouses. The USDA *pretest program* enjoins growers who have shipped animals with above-tolerance levels of pesticides (as established by EPA) or animal drugs (animal drug

tolerances are set by FDA) to market in the past, to provide the department with laboratory analyses of livestock samples prior to slaughter. USDA and FDA share responsibility under the FFDCA, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to prevent "adulterated" (chemically contaminated) meat and poultry from entering interstate commerce. USDA refers violations to the FDA for possible prosecution.

The Food and Drug Administration, under the terms of the FFDCA, monitors foods other than meat and poultry for chemical residues. FDA, as described above, has the authority to prosecute growers whose animals have been found violative during USDA monitoring. Chapter IV deals with the regulatory programs of the FDA.

Specific subcommittee findings, conclusions and recommendations are presented at the close of each chapter.

General findings and conclusions are stated in chapter 5.

In his statement that opened the first day of hearings on February 14, 1978, Subcommittee Chairman John E. Moss (D. Cal.), offered this assessment of the problem of toxic substances in food:

> Chemical contamination of food presents an insidious hazard because chemicals are almost impossible for the consumer to detect. He cannot see, smell, or taste them . . . Unlike some other environmental hazards, the consumer has no freedom of choice when it comes to toxic residues in food.[8]

We all have to eat. And because of the nature of chemical contaminants, we are forced to rely on the federal government, with its staff, facilities and legal authority, to protect us against potentially dangerous chemicals we "cannot see, smell, or taste." As this report will illustrate, current government programs and laws are not providing us with adequate protection from the known and unknown hazards of chemically contaminated food.

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[8] "Cancer-Causing Chemicals—Part 2: Chemical Contamination of Food," hearings before the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce of the U.S. House of Representatives, 95th Cong. 2d sess. serial No. 95–118 (hereinafter cited as *Hearings*.)

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Chapter II.—The Environmental Protection Agency's Tolerance-Setting Program

1. BACKGROUND

In 1970, the newly created Environmental Protection Agency (EPA) inherited all responsibility for approving pesticides for use in the United States:

> Pesticide tolerance setting functions, governed by the Federal Food, Drug, and Cosmetic Act (FFDCA) [9] of 1938, were transferred from the Food and Drug Administration (FDA) to the EPA.
>
> The pesticide registration system, administered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947, was moved from the United States Department of Agriculture (USDA) to the EPA.

According to the "pesticide amendment", added to the FFDCA in 1954, pesticide tolerances (maximum amounts of active pesticide ingredients that may be legally present in or on particular foods) are to be set "to the extent necessary to protect the public health." A separate tolerance must be established for each raw agricultural commodity on which the pesticide will be used. The establishment of a tolerance, or an official exemption from the tolerance requirement, is a prerequisite of pesticide registration (licensing for use) under FIFRA. Tolerances are set and registrations are granted by the Registration Division of EPA's Office of Pesticide Programs (OPP).

This chapter will explore the Environmental Protection Agency's tolerance setting system governed by the FFDCA. Registration programs under FIFRA will be discussed as they relate to tolerance setting. The chapter will conclude with a summary of the Subcommittee's findings and its recommendations for programmatic and legislative changes.

2. EPA'S TOLERANCE-SETTING PROGRAM

Five thousand nine hundred and eighty four individual tolerances have been set for 271 pesticides since section 408, "the pesticide amendment", was added to the Federal Food, Drug, and Cosmetic Act in 1954. Nine hundred and forty of the tolerances that have been established over the years are for pesticides now believed to be potential carcinogens (cancer causers). Many other tolerances remain in effect for pesticides that have never been tested for their potential to cause cancer, birth defects, sterility or genetic mutations.

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[9] Federal Food, Drug, and Cosmetic Act, as amended. 21 U.S.C. 346a(b). [FFDCA Section 408(b).]

The following table lists the years in which various safety tests were first required by the government before a pesticide tolerance would be granted:

Testing requirements

	Date first required
Acute toxicity (adverse effects from a single dose. Mortality in 50 percent of the animals exposed)	1954
Subacute toxicity (adverse effects from repeated exposure over a short period of time, usually 90 days)	1954
Chronic feeding-oncogenicity [10] (chronic feeding over most of test animals' lifetimes to determine whether substance induces growth of tumors)	1963
Reproduction (testing to determine whether substance causes adverse effects on animals' abilities to reproduce: size and health of offspring, effects on fertility, etc.)	1963
Teratogenicity [11] (testing to determine whether a substance causes birth defects)	1970
Mutagenicity [12] (testing to determine whether substance causes genetic changes that will be passed on to future generations) [13]	1970

As the table illustrates, prior to 1963 pesticides were only tested for their highly apparent short-range toxic effects before tolerances were established by the government. During the sixties, tests for oncogenicity (ability to induce tumors) and tests to determine effects on reproduction were added. It wasn't until less than a decade ago that the government began to concern itself with a pesticide's power to cause birth defects and permanent genetic mutations.

In a 1975 review that preceded a report to Congress entitled "Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately from Pesticide Hazards?" the General Accounting Office (GAO) randomly selected 36 pesticide chemicals with established tolerances to determine the availability of safety data. Of the 36:

Seven lacked cancer and reproduction studies,
Fourteen lacked birth defect studies, and
Twenty-three lacked mutation studies.[14]

The GAO also reviewed the adequacy of residue (the amount of a pesticide remaining in or on food following normal product use) data for existing tolerances.

Mr. Henry Eschwege, Director of the Community and Economic Development Division of the GAO, testified to the importance of setting tolerances based on realistic residue data during the first day of Subcommittee hearings on February 14, 1978:

> Tolerances set at artificially high levels may subject the public to greater than necessary residues in food. Tolerances set below the residue level expected from proper application of the pesticide may result in excessive residues which would render the food adulterated, and subject to FDA removal from interstate commerce.[15]

In other words, a tolerance level that is higher than necessary could create a needless public health risk while a level that is unrealistically low could result in illegal residues stemming from normal product use.

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[10] Oncogenicity is defined as the power of a substance to incite tumor formation, either benign or malignant, in living tissue.
[11] Teratogenicity is defined as the ability of a substance to induce birth defects by acting on the embryo.
[12] Mutagenicity, defined as the power of a substance to produce permanent, hereditary genetic changes. Genetic mutations may not be apparent for generations.
[13] General Accounting Office Report, "Federal Pesticide Registration Program: Is it Protecting the Public and the Environment Adequately From Pesticide Hazards?" Washington, D.C.: Dec. 4, 1975, pp. 7-8. (Text paraphrased here.)
[14] *Ibid*, p. 9.
[15] *Hearings*, *supra* n. 8. p. 5.

In the 1975 review, GAO studied residue data for 10 common crops (including apples, peaches and beans) for which 143 tolerances had been established. GAO determined that 91 of the 143 tolerances lacked residue data altogether and that,

> Of the remaining 52 tolerances established, only 6 accurately reflected available residue data, 27 were set above and 19 were set below residues remaining on crops.[16]

The nature of these findings, coupled with the EPA's apparent inability to deal effectively with cancer-causing pesticides and safety test data gaps, led the GAO to conclude that it was time for EPA to:

> Review the adequacy of supporting safety and residue data for all existing tolerances and require manufacturers to submit missing data.[17]

EPA responded on September 11, 1975:

> GAO's criticisms are well-founded, and we are very much concerned about tolerance-setting problems. In the recent past our emphasis on the implementation of FIFRA has allowed for insufficient attention to problems identified here. Now that the necessary regulations for registration have been promulgated, we can turn more of our attention to review of the tolerance regulations and procedures, to reassessment of tolerances already regulated, and to a comprehensive evaluation of the whole scientific basis for tolerance setting. We accept and will implement GAO's recommendations in this area.[18] [Emphasis added.]

In November of 1977 the Subcommittee asked the General Accounting Office to conduct a follow-up study to assess the adequacy of actions taken in response to the (1975) recommendations respecting tolerance setting and residue monitoring.

The GAO follow-up study of EPA's tolerance setting program (FDA's monitoring system was also included in the review), was completed in early 1978 at the request of the Subcommittee. At the hearings in February GAO testified that:

1. Safety test and residue data gaps still exist for pesticides with established tolerances. EPA has failed to officially notify registrants that they will be required to supply missing data by any given date. In February of 1976, EPA published a listing in the *Federal Register* of 442 registered pesticides which *lacked safety studies that would require over two years to complete.* As of February 1978, EPA had not directed registrants to begin these studies.

2. EPA has deviated from its own method of computing safety levels for pesticides in certain instances. EPA computes the acceptable daily exposure for residues of each pesticide. The agency then determines the total potential daily exposure based on all tolerances that have been set for that pesticide and an average daily diet estimate for an American male. If the total pesticide residues likely to be found in the daily diet are below the acceptable daily exposure, tolerances established for that pesticide are considered safe. However, the GAO follow-up study found cases in which the total potential daily exposure *exceeded* the acceptable daily exposure. For instance, potential public exposure to toxaphene—a suspect carcinogen—was almost four times the acceptable daily exposure computed by the EPA.

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[16] *Hearings, supra* note 8, p. 5. See also GAO Report, "Federal Pesticide Registration Program: Is it Protecting the Public and the Environment Adequately From Pesticide Hazards?" (Hereinafter cited as *GAO Report.*) pp. 42–43.

[17] *GAO Report supra* note 16, p. 48.

[18] *GAO Report supra* note 16, p. 83.

3. Some registered pesticides have resulted in residues in food for which no tolerance has been set. For example, some uses of chlordane have resulted in residues in milk, while no milk tolerance has been established for chlordane.[19]

Overall, the GAO found that EPA had made "little tangible progress" [20] in reviewing and improving its tolerance setting program in the two years since it agreed to accept and implement GAO's recommendations.[21] Mr. Eschwege pointed to only two agency measures which demonstrated progress in improving EPA's system of approving pesticides for use:

First, EPA has requested that its Science Advisory Board "study the scientific foundations of the entire tolerance setting program." [22] While this is the only tangible progress EPA has made that is directly related to tolerance program reform, waiting for advisory board recommendations can actually have the effect of impeding needed change.

Second, on July 3, 1975, EPA instituted a program entitled "Rebuttable Presumption Against Registration" (RPAR). Under the RPAR program, the reregistrations of pesticides that are known to cause cancer or other serious ill effects are being scrutinized.

However, only pesticides with known hazards are being reviewed—just seven of the 36 chemicals GAO studied in 1975 and found lacking in 44 required safety tests.

The EPA is far behind its projected RPAR schedule. In April of 1976, EPA published a list of 45 chemicals that would be subjected to RPAR proceedings. Final decisions on all 45 chemicals were to be made by October of 1977. However, as of April 17, 1978, only one RPAR proceeding had been completed.

Finally, while an RPAR proceeding may lead to an EPA decision to deny or cancel registration of a pesticide, the registration system is administered under FIFRA rather than FFDCA. Decisions made under FIFRA do not directly affect the tolerance setting system. For instance, tolerances cannot be revoked under the provision of FIFRA. Thus, food products containing residues of cancelled pesticides (registration denied) can be legally sold as long as pesticide tolerances have not been revoked under the FFDCA.

A. Tolerance-setting methodology

Whenever an applicant seeks registration for pesticide use, he or she is required by EPA to simultaneously apply for a tolerance or an exemption from the tolerance requirement for each commodity in which residues of the substance could remain. On Feb. 14, 1978, Steven Jellinek, Assistant Administrator for Toxic Substances at the EPA, explained the process that triggers tolerance-establishment:

> The petitioner—usually the manufacturer of the pesticide in question—proposes to EPA a specific tolerance level for the crop or crops on which the product is to be applied. The petition is backed up by two basic kinds of information: first, chemistry data, showing actual residues after application, how the chemical behaves on the commodity, and the nature of the pesticide breakdown products, as well as the analytical methodology for detecting residues; and second, toxicology data, showing the effects of the chemical on test animals.[23]

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[19] *Hearings, supra* note 8, p. 6, opening statement of Henry Eschwege, General Accounting Office.
[20] *Hearings, supra* note 8, p. 9.
[21] *Ibid.*
[22] *Ibid*, p. 5.
[23] *Ibid*, p. 30.

EPA then sets the tolerance according to two basic principles: that it protect the public health, and that it be set at a level no higher than is necessary to control the pest. EPA's Office of Pesticide Programs uses the toxicology data provided by the manufacturer to test the product for a safe tolerance level according to standard agency methodology. *Potential* exposure to the substance is compared with maximum *permissible* exposure. Permissible exposure is calculated in the following manner:

1. *No Observable Effect Level* (*NOEL*), defined as the "level of a substance administered to a group of experimental animals at which those [adverse] effects observed or measured at higher levels are absent. . . ." Test animals used are usually rats or mice. The NOEL for test animals is expressed in parts per million (ppm). Parts per million are then converted to milligrams per kilogram of body weight per day (mg/kg/day).

2. *Safety Factor or "Factor of 100."* The NOEL in mg/kg/body weight/day is divided by the Safety Factor, usually a factor of 100 because, according to the EPA, "man appears to be 10 times as sensitive to toxic substances as the rat and . . . sickness increases the susceptibility of man to such substances 10 times."

3. *Acceptable Daily Intake* (*ADI*). The ADI is the quotient obtained when the NOEL is divided by the Safety Factor.

4. *The Maximum Permissible Intake* (*MPI*) is determined by multiplying the Acceptable Daily Intake by what the EPA characterizes as the average weight of an adult, 60 kilograms (132 pounds).

The Maximum Permissible Intake (permissible exposure) is then compared with the Theoretical Maximum Residue Contribution (maximum potential exposure) which is determined in the following way:

(*a*) The *Tolerance* proposed by the applicant for pesticide registration is multiplied by

(*b*) The *Food Factor*, which is an estimate of how much of the commodity to be treated with the pesticide will be eaten daily by the average American.

(*c*) This product is then multiplied by the *Daily Diet*, which EPA estimates to be 1500 grams (3.3 pounds).

(*d*) The Proposed Tolerance $\times$ the Food Factor $\times$ the Daily Diet = the *Theoretical Maximum Residue Contribution* (*TMRC*).

If the Theoretical Maximum Residue Contribution does not exceed the Maximum Permissible Intake, then the proposed tolerance is considered to be a safe one according to EPA's methodology.

If multiple tolerances are proposed for a single pesticide ingredient, the EPA totals the Theoretical Maximum Residue Contributions for all commodities on which pesticides will be applied and then compares the sum with the Maximum Permissible Intake. The *total* TMRC's for any given pesticide must not exceed its MPI.

B. Deficiencies in EPA tolerance-setting methodology

There are many problems associated with the tolerance setting process. As we said earlier, EPA does not always apply its tolerance-setting methodology uniformly. However, even flawless adherence to the system would fall far short of providing the public with adequate protection from harmful pesticides.

1. THE TOLERANCE-SETTING PROCESS AND CARCINOGENIC PESTICIDES

At least 25% of all pesticides on the market have shown cancer-causing potential.[24] As the Subcommittee pointed out in October 1976, more than 80% of those 238 active ingredients (which represent approximately one-third of all pesticides on the market in 1976) meeting or exceeding the risk criteria are suspect carcinogens. One-sixth of the established tolerances are for carcinogenic pesticides.

Yet EPA's Steven Jellinek told the Subcommittee on February 14, 1978:

> The basic system for establishing tolerances has been in place for some twenty years now. As we learn more and more about pesticide hazards, areas of uncertainty in the system become apparent. For instance, the system is inappropriate for dealing cleanly with pesticides for which no safe level of exposure can be determined, those of a potential carcinogen, for example.[25]

Mr. Jellinek was not the first EPA official to admit that the tolerance setting process is inappropriate for carcinogens. The tolerance setting methodology pivots on the No Observable Effect Level (NOEL) concept. The NOEL is the amount of a pesticide dose which does not produce any adverse effects in test animals. On June 30, 1977, Andrew M. Breidenbach, former Special Assistant to EPA Administrator Douglas M. Costle, told the Senate Agriculture Research and General Legislation Subcommittee:

> "The existing tolerance setting system, based on the establishment of a NOEL, has not been designed to handle pesticide residues for which no safety threshold can be determined. The question then arises whether a tolerance should be set for a pesticide which is a potential carcinogen, for example, since it is not possible to establish a NOEL for such a substance." [26]

The answer to this question is—"no, tolerances should not be established for potential carcinogens". Then what about the 940 tolerances representing a third of all pesticides, which *are* suspect carcinogens and *have* tolerances? These tolerances should be immediately reassessed.

However, tolerance reassessment is a low priority at the EPA. The agency's pesticide programs operate on an annual budget of $60.7 million (FY 1979) with an allotment of 1,013 positions. Not one of these positions is devoted exclusively to tolerance reassessment. The EPA told the Subcommittee on February 14:

> Several proposals for tolerance reassessment of different levels of effort were made in the FY 77 budget process. Two positions were finally allotted for tolerance reassessment. These positions were not filled, however.[27]

In defense of its lack of action with respect to tolerance reassessment, the EPA points to its RPAR proceedings and its proposed re-registration system.[28] EPA says the reregistration effort may take fifteen years to complete,[29] and we have already said that the RPAR program is behind schedule. Both RPAR and pesticide registration are administered under the Federal Insecticide, Fungicide and Ro-

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[24] See report by the Subcommittee on Oversight and Investigations, "Federal Regulation and Regulatory Reform," U.S. Government Printing Office, Washington, D.C., October 1976, p. 142.

[25] *Hearings, supra*, note 8, p. 31.

[26] Statement of Andrew W. Breidenbach, Special Assistant to the Administrator, Environmental Protection Agency, before the Agricultural Research and General Legislation Subcommittee of the Committee on Agriculture, Nutrition and Forestry, U.S. Senate, June 30, 1977.

[27] *Hearings, supra*, note 8, p. 86.

[28] *Ibid*, p. 31-32.

[29] *Ibid*, p. 82.

denticide Act, which is not as stringently protective of human health as the Federal Food, Drug, and Cosmetic Act, which governs the tolerance system. As Mr. Jellinek explained to the Subcommittee:

> FFDCA speaks to "safe for human consumption." FIFRA demands that EPA balance risks and benefits in reaching decisions that a pesticide does not cause an unreasonable adverse effect in humans or the environment.[30]

EPA clearly supports a trend away from the strictly health-oriented language of the FFDCA, toward the less stringent health-related provisions of FIFRA, as is evident from the February 14 hearing record. Mr. Jellinek testified:

> I think what I said is that we've decided as an agency to make these basic decisions under FIFRA and to accompany that decision with a decision on the tolerance.[31]

Therefore, the only action EPA has taken publicly that relates directly to tolerance setting as defined by the Federal Food, Drug, and Cosmetic Act, is the agency's request to its Science Advisory Board to review the tolerance system and make recommendations. EPA says it expects a draft of this recommendation by the end of 1978.[32]

2. FALLIBILITY OF THE FOOD FACTOR

The "Food Factor" is an important element of the tolerance setting mechanism. In determining the Food Factor, EPA relies on data gathered by the United States Department of Agriculture during the 1960's and printed in USDA's report series entitled, "Consumption of Food in the United States." [33]

With few exceptions, USDA consumption data used by EPA are based on simple division: the total yield of a given commodity is divided by the population of the United States. EPA then divides the quotient calculated by the USDA by the number of days in a year to obtain the amount of per capita daily consumption known as the Food Factor.

This system is fallible because it averages consumers of a particular food with non-consumers. According to a Library of Congress report on the consumption statistics EPA uses in esablishing tolerances:

> It is well known that the per capita consumption of many foods varies considerably from person to person. Income and household size are two important factors which affect the amounts of individual foods consumed per person. Age, sex, region of the country, food preference, season of the year, and farm or nonfarm residence are other factors that affect the amount of each food a person eats.[34]

For instance, using consumption data from a USDA 1965–66 household survey, only one in twenty families consumes fresh pears. Since EPA's official Food Factor is based on average consumption for the *total population*, the amount of pears actually consumed by an individual may be underestimated by as much as 2,000 percent.

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[30] *Ibid*, p. 32–33.
[31] *Ibid* p. 88.
[32] *Ibid.*
[33] U.S. Department of Agricultural Research Service, "Household Food Consumption Survey 1965–66" See Reports. Nos. 1, 6, 11, and 12.
[34] Library of Congress Congressional Research Service, "Considerations in the Use of USDA Food Consumption Statistics in the setting of Pesticide Tolerances by the Environmental Protection Agency," a report prepared at the request of the Subcommittee on Oversight and Investigations, Feb. 13, 1978, p. 2.

EPA assumes that no more than 7.5 ounces of the following foods are consumed per person *per year:*

Artichokes,	Eggplant,	Mollasses,	Safflower,
Avocados,	Figs,	Mushrooms,	Summer Squash,
Barley,	Honeydew Melons,	Nectarines,	Swiss Chard,
Black-eyed Peas,	Hops,	Okra,	Tangelos,
Coconut,	Horseradish,	Plums,	Tangerines,
Crabapples,	Kale,	Radishes,	Turnips,
Cranberries,	Mangoes,	Raspberries,	Walnuts,
Dates,	Millet,	Rye,	Winter Squash.[35]

These levels border on the absured, as Lowell Dodge, Counsel to the Subcommittee, pointed out during the hearings:

> . . . you only need to eat 7.5 ounces of avocado [per year], for instance—about the amount of avocado that is contained in a single avocado—before you begin to exceed the level that EPA assumes as the usage level in setting up tolerances.[36]

Mr. Dodge went on to cite other examples of distorted annual per capita consumption statistics used by the EPA: seven and one-half ounces of brussel sprouts; seven and one-half ounces of tangerines (about two fruits). For actual consumers of these goods, amount of consumption is much higher.

Perhaps the most frightening ramification of EPA's faulty system for computing the Food Factor involves infant consumption of milk. Infants under the age of one consume twice as much milk as the average individual. A tolerance level that is based on a figure that underestimates consumption by one-half, and is computed using the average weight of an adult (132 pounds), is hardly adequate for infants.

The EPA claims that, "When a proposed milk tolerance is revised, the TMRC (Theoretical Maximum Residue Contribution) is calculated for infants in particular, averaging a total milk diet."[37] However, several toxicologists in EPA's Toxicology Branch of the Registration Division Office of Pesticide Programs, admitted during a subcommittee staff survey that they do not routinely consider high consumption of milk by infants in setting milk tolerances.[38]

EPA officials admit that milk may warrant more special attention to safety testing and tolerance setting than it is presently accorded. In a memo dated January, 1978, entitled "Milk Tolerances", Mr. Edwin L. Johnson, Deputy Assistant Administrator of EPA's Office of Pesticide Programs, wrote:

> Milk, as a prime food for infants and children, an important item in the diet of pregnant and lactating women, and a component of the diet of millions of consumers throughout their life span, may deserve special handling. . . .[39]

Mr. Johnson went on to say:

> Because the fetus and the neonate [newborn] are at a special risk, due to immaturity of body structures and functions, special studies which may feature lifetime exposure, beginning before conception; studies in which exposure begins at birth; and special reproduction and teratologic studies may be needed to support safety of milk additives, including pesticides.[40]

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[35] See App. III.
[36] *Hearings*, *supra* note 8, p. 89.
[37] *Ibid*, p. 48.
[38] Survey conducted by subcommittee staff in Feb. 1978.
[39] *Hearings*, *supra* note 8, p. 57, memo entitled "Milk Tolerances" from: Edwin L. Johnson, Deputy Assistant Administrator, EPA Office of Pesticide Programs, to: Dr. Norton Nelson, Chairman EPA Environmental Health Advisory Committee.
[40] *Ibid*, p. 58.

The memo on milk tolerances has been submitted to EPA's Science Advisory Board for its overall review of the tolerance system. The Board is expected to make recommendations concerning milk tolerances and other EPA tolerance setting policies following its review.

The Library of Congress report on consumption data suggests:

> EPA could better identify groups of consumers with high potential intakes of pesticide residues by basing its calculations on a high level of food consumption rather than on averages.[41]

The Library of Congress report goes on to say that USDA statistics are available to the EPA that identify high level consumption groups by age and sex. For example, according to 1965–66 statistics, high consumption groups include:

> Males 15–17 years for cream, ice cream, bread, rolls and biscuits; males 18–19 years for pork and some baked goods; males 20–34 for beef, eggs, poultry, potatoes and tomatoes; males 35–54 for dark green vegetable mixtures; females 55–64 for citrus fruits; and males and females under one for milk.[42]

Nevertheless, these figures still treat consumers and non-consumers alike. If non-consumers of particular foods in each age-sex group were to be excluded, the figures would more accurately reflect actual consumption levels. Again, the Library of Congress report states:

> The highest reported consumption of fish and shellfish is 18 grams per person per day for males 55–64 years, 80 percent more than the average for all individuals. However, only 10.8 percent of the males in this age group reported eating fish and shellfish. Thus, the average consumption of those persons actually eating fish and shellfish is several times the reported average. It is on the order of 167 grams per day.[43]

In 1977, when the EPA revised the "action levels" (legal amounts of chemical residues that may be present in foods for which no tolerances have been established) for the pesticide Kepone in seafood, the agency assumed that high consumers would eat no more than an average of 19.8 grams of seafood per day. Kepone is a suspect carcinogen pesticide that was manufactured at Hopewell, Virginia, from 1966 to 1975. The substance has contaminated fish and shellfish in the James River and parts of the Chesapeake Bay in Maryland and Virginia. Since the Kepone-affected area boasts a well established local seafood industry, it is likely that the actual per capita amount of seafood eaten by the highest seafood consumers in the area more closely approximates the Library of Congress estimate, which is more than 8 times as high as the figure used by EPA.

Finally, EPA's use of consumption statistics that are more than a decade old is ill advised because eating habits are changing in the United States. The Library of Congress report states:

> Since 1965 we have seen some major shifts in food consumption in the U.S. Pork, egg, milk and cream, butter and lard, sugar, and wheat flour consumption has declined on a pounds per capita basis. And consumption of poultry, chicken, cheese, margarine, shortening and oils, fresh fruits, fresh and frozen vegetables, and corn syrup and sweeteners has increased.[44]

A new 1977–78 household consumption survey, similar to the one conducted in the sixties, is underway at the USDA. However, data from this survey will not be available for at least several months.

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[41] Library of Congress report, "*Considerations in the Use of USDA Consumption Statistics in the Setting of Pesticide Tolerances by the Environmental Protection Agency*," p. 5.
[42] See *Ibid.*, p. 6.
[43] *Ibid.*, pp. 6 and 7.
[44] *Ibid.*, p. 7.

3. EXEMPTIONS FROM THE TOLERANCE SETTING REQUIREMENT

Under the law, EPA has the authority to exempt certain pesticides from the tolerance setting requirement. According to section 408 of the Federal Food, Drug, and Cosmetic Act:

> The Administrator shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health.[45]

Sections 180.1001–180.1035 of the Code of Federal Regulations list the pesticide ingredients that the Environmental Protection Agency and the Food and Drug Administration (prior to 1970) have exempted from the tolerance requirement. The list of exempt substances includes:

> More than 1,000 "inert" ingredients. (Chemicals classified as inert are not necessarily unreactive. Classification as "inert" simply means that a substance does not have active pesticide properties.) "Inert" chemicals approved for use are automatically tolerance exempt.[46]
>
> Approximately 50 ingredients that are active pesticides. (Some are exempt for general agricultural use. Others are exempt only for specific uses.) [47]

The law states that an exemption is to be granted only when "a tolerance is not necessary to protect the public health." Part (a) of section 180.1001 of the Code of Federal Regulations, which introduces the list of exempt chemicals, states a clear interpretation of the FFDCA:

> An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health.[48]

During a public meeting of the Study Group on Pesticide Tolerances of EPA's Science Advisory Board, held on June 27 and 28, 1978, Joseph Cummings, Chief of the Chemistry Branch of EPA's Registration Division, Office of Pesticide Programs, stated his concern about some tolerance exemptions for both "active" and "inert" pesticide ingredients that are now known to pose health risks. Mr. Cummings cited Carbon Tetrachloride and Ethylene Dibromide as examples.

Carbon Tetrachloride, an active pesticide which is exempt from the tolerance requirement when used as a fumigant[49] for barley, corn, oats, popcorn, rice, rye, sorghum, and wheat, is currently undergoing EPA's pre-RPAR review process. The substance has been shown to be oncogenic, mutagenic, teratogenic and potentially carcinogenic.[50] In addition it has shown embryotoxic[51] and hepatoxic[52] potential.

Ethylene Dibromide, another active pesticide which is exempt for specific fumigant uses, is currently undergoing the RPAR process. Ethylene Dibromide is a known mutagen and tumor inducer that has also caused reproductive problems in bulls, mice, rats and chickens.

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[45] Federal Food, Drug, and Cosmetic Act, as amended; 21 U.S.C. 346a(c). [FFDCA sec. 498(b).]
[46] Code of Federal Regulations, sec. 180.1001.
[47] Code of Federal Regulations, secs. 180.1002–180.1035.
[48] Code of Federal Regulations, sec. 180.1001.
[49] Fumigants are vaporized pesticides, usually applied post-harvest in confined spaces to kill fungus or insect pests.
[50] See footnotes 10–12 for definitions.
[51] Possessing qualities toxic to the embryo.
[52] Possessing qualities toxic to liver cells.

Chloroform, a suspect carcinogen, which is also one of EPA's top priority RPAR substances, is tolerance exempt for use as a fumigant on certain grain crops. Chloroform has demonstrated oncogenic power in rats and mice. It is also suspected of causing kidney and liver damage.

All of the above highly hazardous substances were thought to pose no risk to the public health when they were exempted from the tolerance requirement for use as fumigants. Although chemicals that have demonstrated potential to cause serious health problems *may pose no risk* when they are used for the purposes for which they were exempted for, EPA cannot guarantee that the public *is* at no risk with respect to certain tolerance-exempt chemical agents.

For example, residues of the fumigant Ethylene Dibromide have been found in citrus fruit peel. While the government once thought that fumigants would not result in harmful residues in food, this theory has been proven false.

In 1976, EPA commissioned Potomac Research, Inc. to identify all "inert" (and therefore tolerance exempt) chemicals in pesticides that posed potential health or environmental hazards. The results of this investigation were printed on September 30, 1977, in a report entitled *The Investigation and Classification of Inert Ingredients in Pesticide Formulations*.[53] The introduction to the report states:

> In evaluating the safety of pesticides, toxicologists have required extensive long and short term toxicological testing of the active ingredients of the pesticide. Generally little or no toxicological information on other ingredients of the formulation, i.e., the inerts, has been required. The 1974 discovery that vinyl chloride, an inert propellant used in some pesticide aerosols, causes a rare form of liver cancer brought about the necessity for thoroughly evaluating the potential danger of inert ingredients.[54]

Potomac Research investigators evaluated all inert pesticide ingredients for their toxicological effects on health and the environment and classified them in six categories accordingly. Fifty-two chemicals were listed in classes "1" and "2", defined as follows:

> Class 1—This category of inerts contains those found to have chemical, toxicological or environmental characteristics that require immediate attention.
>
> Class 2—Available data indicate probable cause for alarm because chemical structure is similar to a known toxicant, or a metabolic environmental pathway may result in breakdown to known toxicant, or irreversible chronic effects are known, e.g., neurotoxicity, irreversible eye damage, skin sensitization, etc. Massive fish kills or other environmental effects also triggers [sic] this category."[55]

Among those 52 inert ingredients classified In Classes 1 and 2 was Dioxane (Class 1), used as a solvent and cosolvent in pesticides. According to Potomac Research, Dioxane also functions as a solvent in "resins, oils, waxes and some dyes. and as a solvent for electrical, agricultural and biomedical intermediates and for adhesives, sealants, cosmetics, pharmaceuticals, rubber chemicals and surface coatings."[56]

Dioxane is a known carcinogen that, according to the report:

> produced malignant tumors of the nasal cavity and liver in rats and tumors of the liver and gall bladder in guinea pigs. It was also active as a promoter in ati two-stage skin carcinogenesis study in mice.[57]

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[53] Potomac Research Inc., "The Investigation and Classification of Inert Ingredients in Pesticide Formulations", EPA contract 68-01-3431, Sept. 30, 1977.
[54] *Ibid.*, p. 1.
[55] *Ibid.*, p. 33.
[56] "Inert Ingredients of Pesticide Formulations", EPA contract 68-01-3431, EPA accession number and name: 000766 Dioxane (data and evaluations for particular inert ingredients accompany report mentioned above.)
[57] *Ibid.*

In addition:

Human deaths from accidental poisoning through inhalation and skin absorption of 1,4-dioxane have been reported.[58]

One worker died as a result of a week's exposure to 500 parts per million of 1,4-dioxane. An autopsy revealed liver, kidney and brain damage. Five other acute deaths due to Dioxane exposure have been attributed to hemorrhagic nephritis (kidney hemorrhage) and liver-necrosis.[59]

Phenarsazine oxide is another tolerance exempt substance that was given a "Class 1" rating in the Potomac Research report. This substance is similar in structure and composition to Phenarsazine chloride, which is used as a war gas, producing severe pain in the chest, nose and sinuses, coughing, vomiting, and sensory distrubances. Phenarsazine Oxide is an arsenic compound. According to the report, "The evidence is now overwhelming that arsenic is a carcinogen in man".[60]

Clinical reports have documented an association of chronic arsenicism with skin cancer in vineyard workers. The risk of lung cancer is clearly increased in certain smelter workers who inhale high levels of inorganic arsenic compounds.[61]

Triethylamine is another inert pesticide chemical listed as a potential health hazard in the report.[62] Nitrosamines, which are powerful carcinogens, are produced when Triethylamine reacts with nitrous acid. According to Potomac Research, Inc.:

Under certain circumstances, triethylamine can react with nitrites to produce a highly potent carcinogen, the corresponding nitrosamine. An example using morpholine along with nitrites in the diet with a consequent high frequency of tumor production has been the subject of several publications. The controversial addition of nitrites to bacon and sausages is another example. Because of the inherently explosive publicity that could be generated by others, it would be highly desirable for EPA to have investigations underway to determine the circumstances that could lead to nitrosamine production from triethylamine.[63]

Two additional major problems associated with tolerance exemptions were spelled out by Mr. Cummings and Dr. Reto Engler of the Toxicology Branch, OPP, at EPA's June Science Advisory Board meeting on pesticide tolerances:[64]

When an exempted pesticide ingredient is misused, it is very difficult for the EPA to take legal action. A tolerance-exempt pesticide ingredient is not legally violative at any level. While the FDA may recommend that EPA set an "action level" (a legal limit that is set when high residues of a chemical are found in situations where no appropriate tolerance exists), such a procedure is remedial at best rather than preventive and does not assure effective protection of the public health.

Even more serious, however, is a problem involving monitoring and detection. The FDA is required to monitor pesticides with tolerances for violative levels of residues in foods. When a petitioner applies for a tolerance, he or she is required to submit an effective method for detecting residues of the pesticide chemical and

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[58] *Ibid.*

[59] The subcommittee learned during a followup investigation (September 1978) that, while no "inert" pesticide formulations have yet undergone the RPAR review process, 1, 4-dioxape is 1 of 7 inerts that have been accepted for "pre-RRAR" assessment. However, as of Sept. 25, 1978. 1, 4-dioxane still had not been assigned to any particular scientist for consideration. Other inerts accepted for pre-RPAR review status are asbestos, ethylene diamine, tetraacetic acid, maleic anhydride, 2-Imidazolionethione (ETU), triethylamine, and triethyl phosphate. The latter three, like 1, 4-dioxane, have not yet been assigned to EPA personnel. As stated earlier in this report, the RPAR process is proceeding slowly.

[60] Potomac Research, Inc., "Inert Ingredients of Pesticide Formulations" EPA accession number and name: 000419 phenarsazine oxide.

[61] *Ibid.*

[62] See footnote 59.

[63] Potomac Research, Inc., "Inert Ingredients of Pesticide Formulations", EPA accession number and name: 001085 triethylamine.

[64] Meeting held at EPA headquarters, June 27-28, 1978.

its metabolites on the crop for which he or she is requesting the tolerance. But when the EPA exempts a pesticide from the tolerance requirement, the agency also exempts the petitioner from having to provide a detection method for residues. Therefore, the Food and Drug Administration is not supplied with a means for monitoring food for the exempt pesticide ingredient.

Thus, when a potential health risk does develop involving an exempt pesticide chemical, unless the problem reaches serious and immediately evident proportions, it is apt to go unnoticed by the federal government. Because cancer and other ill effects may take many years to develop, with no signs of danger present in the interim, unmonitored and potentially hazardous chemicals in our food may, be causing as yet unrecognizable damaging health effects.

(*a*) *Other deviations from standard tolerance setting*

During its 1975 review of EPA's pesticide programs, the General Accounting Office found numerous examples of pesticides that were not officially exempted from the tolerance requirement, but were nevertheless marketed without prior establishment of proper tolerances.

GAO's 1974 report, *Federal Pesticide Registration Program: Is it Protecting the Environment Adequately from Pesticide Hazards?* illustrated on a common tolerance setting deviation:

> EPA has established a system of interim tolerances to allow using a pesticide while the review of the tolerance petition is in progress. Interim tolerances were usually established when (1) questions of safety existed, (2) inadequate data was provided on residue levels, and (3) petitioners submitted no data to support the safety of the proposed uses. Such tolerances are not consistent with EPA's mandate to protect the public health.[65]

GAO based these findings on an overall study of the interim tolerance system, with specific attention given to six individual cases. GAO's recommendations to EPA regarding interim tolerances, contained in the 1975 report, included the following:

> [EPA should] Reassess the need for and adequacy of data submissions for all interim tolerances; interim tolerances found unnecessary or lacking sufficient data should be canceled if the data is not submitted by a set deadline.[66]

On September 11, 1975, EPA agreed to "accept" and "implement" the recommendations contained in the GAO report.[67]

More than two years later, in November of 1977, this Subcommittee asked the Government Accounting Office to conduct a follow-up study to assess the adequacy of EPA's response to the 1975 recommendations.

During the follow-up study, GAO reexamined the six individual cases that were singled out in the 1975 review. As of January 1978, one of the interim tolerances had expired, two were converted to permanent tolerances, while three retained interim tolerance status. EPA told GAO that the three interim tolerances which remained in effect had not been canceled or converted to permanent status because *data gaps still existed.*[68]

GAO Community and Economic Development Division Director, Henry Eschwege, explained another serious EPA deviation from the standard tolerance setting requirement to the Subcommittee on February 14:

> We [GAO] had reported that in June 1972 EPA's toxicology branch strongly objected to the continued registration of chlordane, endrin, heptachlor, and

[65] GAO report, *supra* note 16, at p. 51.
[66] *Ibid.*, p. 65.
[67] See *Ibid.*, App. I, p. 83.
[68] *Hearings*, *supra* note 8, p. 7.

silvex for certain uses because available toxicity data did not support the proposed tolerances or because residue data was insufficient to determind appropriate tolerances. However, the Office of Pesticide Programs overruled the toxicology branch, stating that absence of a tolerance did not preclude registration of the uses and that there seemed to be only a weak case for cancellation.

As of January 1978, EPA had not set tolerances for any of the questioned uses of chlordane, endrin, heptachlor, and silvex—all of which are suspected of causing cancer and other tumors. The manufacture of chlordane and heptachlor was suspended on July 30, 1975, but as yet the registrations have not been canceled. Further, endrin is undergoing EPA scientific scrutiny to determine whether cancellation action is warranted and silvex is being considered for similar scrutiny.[69]

Deviations from the tolerance setting requirement of the FFDCA are allowing pesticides which may be health risks to remain on the market. While the law is written to exempt only innocuous substances from the tolerance setting requirement, EPA has a history of interpreting the statute to exempt some which may pose major health risks.

3. SUMMARY OF SUBCOMMITTEE FINDINGS AND CONCLUSIONS CONCERNING EPA TOLERANCE SETTING

The Subcommittee concludes that EPA is not providing the American public with adequate protection from the potentially harmful effects of many pesticides. The safe use of pesticides is contingent upon a strong and effective tolerance setting program. Although evidence continues to accumulate that at least 25% of all marketed pesticides are potentially carcinogenic, EPA has not made use of its Congressional mandate to protect the public.

Moreover, EPA has failed to commit the resources necessary to properly protect the public. Not one position out of the more than 1,000 allotted jobs in EPA's pesticide programs is devoted specifically to tolerance reassessment.

Additionally, the action that EPA has proposed to take with regard to the Science Advisory Board is wholely inadequate and may serve to delay the direct regulatory action which EPA must take. EPA should not use the deliberations of the Science Advisory Board as an excuse for inaction.

More specifically, the Subcommittee finds that:

1. One-sixth of established tolerances are for pesticide ingredients that may be classified as suspect carcinogens. Many scientists now believe that even low levels of suspect carcinogens cannot be consumed safely. Yet, EPA continues to employ a system for tolerance setting which ignores this potential danger and to establish tolerances for suspect carcinogens.

2. EPA files are replete with safety test data gaps. EPA admitted in 1975 that at least 442 registered pesticides lacked important safety data. Studies indicate that many pesticides which result in chemical residues in food and animal feed have *never* been tested for their potential to cause cancer, birth defects, and genetic mutations. Because test data for teratogenicity was not required until 1963 and data for mutagenicity was not required until 1970, most pesticides registered before those dates lack proper safety test data. Additionally most of these pesticides have not been reassessed. EPA has not taken sufficient action to correct this situation.

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[69] *Ibid*, pp. 6-7.

3. Some pesticide ingredients that are now known to pose potential health problems have been exempted or partially exempted from the formal tolerance requirement. While the Federal Food, Drug and Cosmetical Act allows exemption for chemicals that are judged safe when used for certain purposes, recent findings have linked the use of some previously exempt chemicals to increased health risks. Moreover, EPA has a practice of granting "interim tolerances" for some pesticides absent safety test data. Interim tolerances exist today for some chemical pesticides that have have never been proven safe. The Subcommittee finds this practice ill-advised and contrary to the statutory mandate.

4. The average per capita daily consumption statistics which EPA uses as its "Food Factor" in establishing tolerances are inaccurate and outdated. These figures which allegedly reflect average consumption for specific food stuffs for the entire U.S. population are based on studies conducted by the U.S. Department of Agriculture over ten years ago and do not reflect significant changes in the eating patterns of Americans which have taken place over this period. Additionally, the Subcommittee found numerous examples of tolerance levels which are based on grossly underestimated consumption levels. Tolerances based on these statistics do not provide consumers with proper protection from potentially unsafe pesticide residues.

5. Pesticide tolerance levels are often higher or lower than the actual amount of residue which may be found in or on commodities on which the chemicals have been applied. Those tolerances that are not based on accurate residue data are not useful either for assuring public protection for or legal enforcement of proper pesticide use.

6. In 1975, EPA agreed to "accept" and "implement" Government Accounting Office (GAO) recommendations designed to rectify program inadequacies and to improve the tolerance setting system. However, as of February 1978, GAO was forced to conclude that EPA had made "little tangible progress" toward implementing GAO recommendations and thereby had failed to significantly improve its tolerance setting program.

7. The Federal Food, Drug, and Cosmetic Act protects the public from potential cancer-causing chemical food additives. However, the Federal Food, Drug and Cosmetic Act (FFDCA) does not apply to the tolerance setting program. EPA sets tolerances based upon the less protective legislative language of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFFRA). The Subcommittee finds that this process lessens public protection.

8. Required safety tests for pesticides (tests for cancer, birth defects, etc.) are often conducted by or for parties which have a vested interest in marketing the pesticide and not by an objective scientific group with no commercial interest in the sale of the product. There is no federal compliance testing program to evaluate these data. As a result, EPA is forced to set many tolerances on unverified test data which may not fully assess the potential dangers of the pesticide in question.

4. SUBCOMMITTEE RECOMMENDATIONS CONCERNING EPA TOLERANCE SETTING PROGRAM

A. The Subcommittee recommends that Congress:

1. Consider enacting legislation making it unlawful to use potentially carcinogenic, mutagenic and teratogenic pesticides on raw agricultural products, unless it can be established that no residues of these products or potentially harmful metabolites from these products remain on the food.

2. Provide additional funds to EPA for safety reevaluation of pesticides. This program should provide priority review for pesticide products which may pose significant health risks to the public.

3. Consider legislation to place the tolerance setting responsibilities of EPA under the authority of another Federal agency more sensitive to public safety in the event that EPA continues to maladminister the program.

B. The Subcommittee recommends that EPA:

1. Cancel tolerances for pesticides which result in potentially carcinogenic, mutagenic, and teratogenic residues in or on raw food stuffs. EPA should establish a program and specific timetable to accomplish this as soon as possible.

2. Require from manufacturers all safety test and residue data be supplied within a specific period of time.

3. Begin an immediate and intensive reassessment of all tolerances through its Office of Pesticide Programs. Positions devoted solely to tolerance reassessment should be created and filled.

4. Reassess all tolerance exemptions. Substances that were granted exemptions from the tolerance requirement before carcinogenicity and other ill effects were linked to pesticides, should have their tolerances revoked if evidence shows that such substances are potentially hazardous.

5. Discontinue the practice of exempting all "inert" pesticide ingredients from the tolerance requirement. EPA should develop a system for proving "inert" pesticide ingredients safe prior to approving them for use. Such a system should go into effect no later than January of 1980.

6. Closely scrutinize all residue data for existing tolerances as part of its tolerance reassessment. Tolerances which do not correspond to updated and accurate measurements of residues left on crops following proper pesticide application should be readjusted. If it is necessary to raise tolerance levels to support data indicating the actual amounts of residues found on crops, new safety tests should be required which reflect the increase in the level of residue present. An increase in the tolerance should not be approved unless it can be proven that the new level will not adversely affect public health.

7. Change its method of computing the "Food Factor." The highest per capita daily consumption groups, based on age, sex and geographic information rather than national averages, should be considered in establishing Food Factors. All infant foods, including milk, should be given special consideration. If the EPA is to continue to use data gathered by the U.S. Department of Agriculture, that data should be tailored specifically to identification of highest risk consumers for specific foods.

8. Develop a workable monitoring system for safety tests conducted by industry. One solution could be to establish a system of government-approved independent private laboratories. EPA should develop standards for such laboratories utilizing objective scientific testing criteria.

9. Abandon immediately the practice of issuing "interim tolerances." A pesticide that has not been proven safe or is suspected of posing a health risk does not belong on the market. Interim tolerances should be revoked for pesticides that lack test data.

10. Cancel tolerances for pesticides which do not degrade within a specified period of time and tolerances for those which degrade into dangerous metabolites. Since tomorrow's scientists may prove today's chemicals unsafe, only readily and safely degradable pesticide ingredients should be approved for use in the future. EPA should develop a firm policy concerning pesticide decomposition time and apply it to the tolerance setting program.

Chapter III

United States Department of Agriculture (USDA): Chemical Residue Monitoring of Meat and Poultry

1. BACKGROUND

The United States Department of Agriculture (USDA) shares responsibility, with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), for protecting the American public against harmful chemical residues in food. USDA, which is responsible for ensuring that meat and poultry are kept off the market when they contain unsafe levels of chemical residues, conducts two residue monitoring programs: the "random sample" program and the "pretest", "hold and test" or "surveillance" program.

Under the random sample monitoring program, USDA inspectors collect tissue samples from a percentage of randomly selected animals in slaughterhouses. USDA then analyzes these samples for residues of pesticides, animal drugs, and environmental contaminants. If a sample exceeds an established tolerence (maximum amount of a chemical that may be legally present in a particular commodity), USDA reports the violation to the FDA for investigation and possible prosecution. Cases of suspected pesticide misuse are reported to EPA as well. Pesticide tolerances for meat and poultry are established by the EPA and tolerances for drugs administered to animals are set by FDA.

Under the "pretest", "hold and test" or "surveillance" program, USDA orders a grower to submit samples from his or her herd for laboratory analysis when (1) outward signs of chemical contamination are evident in animals, (2) a grower has shipped animals with illegal residues to slaughter in the past, or (3) the USDA is conducting a special survey.

This chapter will evaluate the United States Department of Agriculture's monitoring programs for chemical residues in meat and poultry. The Subcommittee's findings, conclusions and recommendations will be presented at the close of the chapter.

2. USDA'S MONITORING PROGRAMS FOR CHEMICAL RESIDUES IN MEAT AND POULTRY

On February 24, 1978, Carol Tucker Foreman, Assistant Secretary for Food and Consumer Services of the United States Department of Agriculture, offered testimony before the Subcommittee concerning USDA's monitoring programs for chemical residues in meat and poultry. Ms. Foreman explained USDA's jurisdiction to the Subcommittee:

> Under the terms of the Meat and Poultry Inspection Act, meat and poultry products are adulterated, and, therefore, are prohibited for use as human food if they contain more than permitted quantities of literally scores of chemical substances.

These chemical substances include pesticides, trace elements, drugs, feed additives, and industrial chemicals which may be harmful to human health.

Our job at USDA is to devise means to make sure harmful residues of these chemicals are not present in meat and poultry products.[70]

However, Ms. Foreman acknowledged, "We have not been as successful in controlling these residue problems as we should be," [71] and she admitted later in her testimony, "There are serious weaknesses in our program." [72]

At least 143 pesticides and drugs are known to leave chemical residues in meat and poultry. Pesticides remaining as residues in animal feed crops may be ingested by livestock and stored in their tissues. Pesticides can result in residues in meat both when they are applied directly on feed crops and when they are present as general environmental contaminants.

Animal drugs are used by growers nationwide. Drugs administered to livestock, which include antibiotics and sulfas, are often misused by growers, leaving illegal residues in animal tissues and subsequently in meat.

Forty of the animal drugs and pesticides known to occur as residues in meat and poultry are suspect carcinogens. Eighteen are suspected of causing birth defects. Yet only 46 of the 143 drugs and pesticides occurring in edible animal tissues are monitored by the USDA. The following table lists the animal drugs and pesticides suspected of causing cancer and birth defects, which remain as residues in food-producing animals but are not monitored in meat and poultry by the federal government:

Suspect Carcinogens Not Monitored in Meat and Poultry by USDA

Animal Drugs.—Chlomadinone Acetate Dimetridazole; Estradiol Benzoate, Estradiol Monopalmitate, Furazolidone, Gentian Violet (not approved for use as an animal drug, but reported used), Melengestrol Acetate, Progesterone, Testosterone.

Pesticides.—Captan, Carbaryl, Chlorobenzilate, Dimethoate, Maneb, Perthane, Piperonulbutoxide, Polyram, Silvex, 2,4–5–T, TDE, Zincion and Maneb Coordination Product, Zineb.

* * * * * * *

Suspect Teratogens (Causers of Birth Defects) not Monitored in Meat and Poultry by USDA

Animal Drugs.—Chlormadinone Acetate, Reserpine.

Pesticides.—Captan, Carbaryl, 2,4–D, Demeton, Diphenlyamine, Fenthion, Maneb, Paraquat, Pentachlorophenol (photodegrades to dioxin), Silver (based on dioxin contaminant), 2,4,5–T (based on dioxin contaminant), Zineb, Benomyl.[73]

Some chemicals which occur as residues in meat and poultry are not monitored because USDA has no means to test produce for their

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[70] *Hearings, supra* note 8, p. 209.
[71] *Ibid.* p. 209.
[72] *Ibid.* p. 212.
[73] Information supplied to the subcommittee by the General Accounting Office. *Hearings, supra* note 8,

presence. Other substances go largely unmonitored because "multi-residue" detection methods (tests for several chemicals simultaneously) do not exist for them and USDA prefers to use only tests that look for many substances at a time.

Ms. Foreman told the Subcommittee that another reason USDA does not monitor many chemicals in meat and poultry is lack of resources and personnel. Less than 1 percent of USDA's total meat and poultry inspection budget of $255,017,000 (FY '78) is devoted to chemical monitoring of meat and poultry.

Equally as serious as the Agriculture Department's failure to test for many chemicals known to occur in meat and poultry, is the following USDA program weakness, described to the Subcommittee by Gregory J. Ahart, Director of the Human Resources Division, General Accounting Office (GAO), on February 16, 1978:

> With few exceptions, neither the Department [USDA] nor FDA can locate and remove from the market raw meat and poultry found to contain illegal residues. Most was sold to the public.[74]

Mr. Ahart went on to explain to the Subcommittee the major reasons why most meat containing illegal levels of chemical substances is not removed from the market:

> "the Department cannot [legally] detain raw meat and poultry pending results of sample analysis unless it has reason to believe the animal is violative.
>
> Meat and poultry are generally marketed within 48 hours after slaughter, and sample analysis usually takes between 6 to 25 days to complete.
>
> Finally, meat from violative animals cannot be identified once the animal has been slaughtered." [75]

By the time the United States Department of Agriculture has discovered a pesticide or animal drug tolerance violation in its random sample monitoring program, the contaminated carcass has already been divided into cuts, shipped to retail stores and sold to unsuspecting customers. Only in rare cases, for instance where a frozen seasonal product such as turkey is concerned, is recovery of contaminated meat or poultry possible. And because meat is not tagged from farm to market, it is often difficult to track down growers suspected of shipping violative animals to market with nothing but USDA slaughterhouse samples as leads.

A. USDA's random sample monitoring program.

Every carcass receiving the USDA inspection stamp is examined for cleanliness and outward signs of health. However, only 1 in 8,000 livestock and 1 in 700,000 poultry are tested in USDA laboratories for chemical residue content, facts which led Chairman Moss to remark during the February 16th hearing:

> A housewife who carefully checks the meat and poultry she buys to determine that it has a USDA-inspected stamp on it is merely getting a product that has been inspected for . . . cleanliness and general health—but in no way does that imply that there has been an inspection to determine whether or not it is an adulterated product because of high residues of the products we've been talking about.[76]

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[74] *Hearing, supra* note 8, p. 99.
[75] *Ibid.*
[76] *Ibid*, p. 204.

Between the years 1974 and 1976, USDA random sample testing for animal drugs, pesticides and general environmental contaminants such as mercury and lead, yielded the following violation rates:

	Percent
Cattle	14. 96
Calves	8. 84
Swine	15. 83
Chickens	5. 08
Turkey	[77] 8. 46

With rare exception, most violative (containing illegal levels of chemical residues) meat products were sold to the public. Using a straight line projection of the amount of meat sampled for various chemical residues versus the total slaughtered and the number found violative, an estimated 1.9 million tons of beef and 1.1 million tons of swine containing illegal levels of chemical residues were sold to the public in 1976. Most of this meat bore the USDA inspection stamp.

Ahart suggested measures that would improve the present USDA Random Sample monitoring program during hearings on February 16:

> If you're going to have the capability to remove, or keep, raw meat and poultry from the market, you have to go one of two ways. You either have to have a system under which you can identify the products through the whole marketing process—the tagging system as we call it here—or you must have the capability—to test the meat and poultry at the slaughterhouse within a 24-hour period before it gets in the marketing distribution chain.[78]

Assistant Secretary Foreman also testified to the need for both rapid residue test procedures and some sort of animal identification system to increase the effectiveness of USDA's Random Sample monitoring program.

B. Food and Drug Administration follow-up

Violations uncovered by USDA residue monitors are reported to the Food and Drug Administration for investigation. FDA has the power to mete out criminal penalties to growers who ship violative animals to market. The bureau also has the authority to recall contaminated meat and poultry. However, the Food and Drug Administration only investigated 37 percent of 3,100 residue violation cases USDA reported to FDA between 1973 and 1976. From 1975 to 1977 FDA prosecuted no residue violators and recalled no meat or poultry.

Because FDA has the power to hand out criminal, but not civil, penalties, the bureau rarely prosecutes a grower unless he or she is a chronic violator. USDA's Random Sample monitoring program infrequently identifies chronic violators.

C. Animal drugs

"The very productivity of American agriculture is based upon the use of chemicals to combat plant and animal diseases",[79] Assistant Secretary Foreman told the Subcommittee on February 24.

"Unfortunately", she said, "we have devised animal husbandry practices, such as close confinement rearing, which cannot be used without drugs to control disease." [80]

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[77] Information supplied to the subcommittee by the General Accounting Office.
[78] *Hearings, supra* note 8, p. 118.
[79] *Ibid,* p. 208.
[80] *Ibid,* p. 209.

Growers routinely administer drugs to their livestock. Sulfa drugs and antibiotics are commonly used to combat or prevent diseases which spread rapidly in the cramped confines of modern feedlots. Drugs are also given to animals to quicken growth.

According to Ms. Foreman, drugs administered to livestock are resulting in a high percentage of illegal residues in meat. Ms. Foreman testified that USDA is experiencing a "major problem with antibiotic residues in dairy cattle and calves":

> We find 10 to 15 percent of the dairy cattle and 4 percent of the calves we test with violative levels of residues.
>
> The causes for this are not completely clear, but is appears to be primarily a situation where farmers are treating sick animals with antibiotics. When the animals fail to respond, some farmers may send them to slaughter without first observing FDA drug withdrawal requirements.[81]

Ms. Foreman also reported that 10 to 15% of the swine tested by USDA contain above-tolerance levels of sulfa drugs in their tissues. Sulfa drugs are added to swine feed to combat a disease called atrophic rhinitis and to increase growth rates.

While the effects on humans who ingest meat contaminated with sulfa drugs and antibiotics are largely unknown, some scientists theorize that residues of these substances in meat could work to lessen the effectiveness of sulfas and antibiotics prescribed for human illnesses. At least two sulfa drugs prescribed for animals, Sulfamethazine and Sulfathiazole, have been linked to cancer.[82]

Of the sixty-seven animal drugs known to leave residues in meat and poultry, only twenty-six are included in USDA's chemical monitoring program and just three have detection methods that meet FDA criteria for follow up investigation and prosecution.

Fifteen animal drugs are suspect carcinogens. Only six of these are part of USDA's official monitoring program and Arsenic is the only potentially carcinogenic drug that has a detection method sufficient for FDA follow-up purposes. The following table lists suspected carcinogenic animal drugs that were monitored in meat by the USDA between 1974 and 1976 with corresponding numbers of samples that were found violative:

Substance	Number tested	Number found violative
Arsenic	6,986	69
Carbadox	2,148	13
Diethylstilbestrol	7,502	47
Ipronidazole	820	17
Sulfas	8,016	[83] 300

A violative sample is one that contains chemical residues at a level higher than the legal tolerance established by the FDA. However, many scientists now believe that *no* level of a carcinogen may be safely ingested by humans.[84] Thus, even samples containing residues of

[81] *Ibid*, p. 211

[82] The Subcommittee held hearings on the potential health threat posed by the misuse of antibiotics in animal feed on September 19 and 23, 1977. The information obtained by this Subcommittee is contained in "Antibiotics in Animal Feeds" hearings before the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 95th Cong., 2d Sess., Ser. No. 95–68.

[83] Information supplied to the subcommittee by the General Accounting Office.

[84] See ch. 2, sec. 2, "The Tolerance-Setting Process and Carcinogenic Pesticides."

potentially carcinogenic animal drugs within legal limits may be of some risk to consumers.

Misuse of an animal drug is not a violation of the Federal Food, Drug, and Cosmetic Act. Regulatory action can only be initiated by the Food and Drug Administration when USDA and FDA can prove the marketing of violative meat. Gragory Ahart of the GAO told the Subcommittee on February 16:

> If misuse of an animal drug were a violation of the FD&C Act [Federal Food, Drug, and Cosmetic Act], FDA could establish a monitoring program designed to identify and correct conditions which could cause residue violations.[85]

Under the current system, violative growers are rarely identified and the combined efforts of FDA and USDA, therefore, do not effectively regulate the occurrence of toxic levels of animal drugs in meat.

D. USDA pretest program

When USDA has reason to believe that a grower has either shipped violative animals to slaughter in the past, or is presently raising animals that contain above-legal levels of pesticides or animal drugs, the Department can order the grower to submit to USDA's "pretest" or "hold and test" residue monitoring program. Under the pretest program, USDA enjoins a grower to provide the Department with laboratory tissue analyses from samples of his or her herd before the suspect animals are sent to the slaughterhouse. A strong program to keep violative animals from reaching the slaughterhouse is essential since, once slaughtered, violative carcasses can rarely be identified in time to stop them from reaching the marketplace.

However, during Subcommittee hearings, Gregory Ahart of the General Accounting Office, characterized USDA's pretest program as, "quite ineffective." [86] Ms. Foreman expressed a concurring opinion based on the following facts which she related to the Subcommittee:

> Some livestock producers have learned to avoid hold and test restrictions by selling their animals in distant markets or by marketing through middlemen.
>
> Since we [USDA] have no authority to quarantine and there is no national animal identification system, there is little we can do to prevent this.[87]

According to Mr. Ahart, a GAO review of three USDA regional offices yielded that "pretest had not been completed by about 800 [nearly two thirds] of the approximately 1300 growers required to submit animals for pretest between January 1973 and November 1976." [88] Because it is so easy for growers to avoid the pretest requirement by selling their animals in distant markets or to middlemen, the pretest program is no more effective than USDA's random sample monitoring program in protecting the public from chemically contaminated meat and poultry. *The USDA has no legal authority to quarantine suspect animals.* Therefore, most growers simply circumvent USDA's orders to submit to the pretest program.

Ms. Foreman told the Subcommittee, "There is no question that we need some sort of quarantine legislation." [89] She explained that a proposal for such legislation was in the process of being drafted at USDA:

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[85] *Hearings supra* note 8, p. 116–117.
[86] *Ibid.*
[87] *Ibid.* p. 212.
[88] *Ibid.* p. 100.
[89] *Ibid.* p. 213.

The kind of authority that we [at USDA] are considering is authority to quarantine herds, flocks, and premises when a residue problem has been identified and the authority to require ownership identification of all livestock.[90]

USDA believes that such authority would help the Department to administer its monitoring programs for chemical residues in meat more effectively.

3. SUBCOMMITTEE FINDINGS AND CONCLUSIONS

A. USDA's "random sample" monitoring program for chemical residues in meat and poultry is seriously inadequate.

(1) A distressingly large number of pesticides and animal drugs known to leave residues in meat and poultry are not monitored by the USDA or any other federal agency. Many pesticides and animal drugs occurring in meat, both monitored and unmonitored, are suspected to cause cancer and/or birth defects.

(2) USDA's tests for chemical residues in food take so long to perform that by the time violative levels of chemicals have been detected, most contaminated meat has already been shipped to market and sold.

(3) The USDA meat and poultry inspection stamp is no guarantee that animal products are not chemically contaminated. The presence of the USDA stamp means only that the food-producing animal was inspected for *visible* signs of health. Most chemically contaminated meat goes to market bearing the USDA inspection stamp.

(4) Less than 1 percent of USDA's total inspection budget is allocated for chemical residue monitoring of meat and poultry, a disproportionately small amount in relation to the seriousness of the health risks posed by ingestion of chemically contaminated food.

B. *USDA's "pretest" monitoring program, under which known violators are ordered to submit laboratory samples from their herds to the Department fails to keep contaminated meat off the market.* The USDA has no authority to quarantine animals that it suspects contain violative levels of chemical residues. Consequently, growers who have been ordered to submit to USDA's pretest program may circumvent the orders by selling their animals in distant markets or to middlemen. No government regulation requires a uniform identification system for livestock sent to slaughter.

C. *Drugs administered to livestock are often misused, resulting in dangerous residues in meat.* According to the USDA, the modern practice of "close confinement rearing" *depends* on the use of drugs such as sulfas and antibiotics to control disease. While such an agricultural system may be economically expedient, it could be creating a national health risk.

4. SUBCOMMITTEE RECOMMENDATIONS

A. The Congress should consider legislation, giving the United States Department of Agriculture the authority to detain animals suspected of containing violative residues of chemicals pending the results of laboratory tests.

B. A national identification system for food-producing animals should be developed so that growers will not be able to avoid submitting animals to USDA's "pretest" program.

[90] *Ibid.* p. 213.

C. USDA should develop and utilize test procedures that can be completed within 48 hours *in the slaughterhouse* for all drugs, pesticides and environmental contaminants that are known to leave residues in meat and poultry. Where multiresidue methods do not exist, USDA should consider using any available means to test for the existence of potentially hazardous contaminants in meat and poultry. No hazardous chemical residues likely to occur in meat should go completely unmonitored.

D. USDA should allocate additional personnel and resources for its residue monitoring programs. The current 1 percent of the Department's total inspection budget which is allocated for residue monitoring is inadequate and should be increased no later than FY 1980.

E. USDA's "random sample" monitoring program should test more animals for chemical residues. Testing only 1 in 8,000 livestock and 1 in 700,000 poultry does not afford a true picture of the extent and nature of chemical contaminants in meat and poultry.

Chapter IV.—Food and Drug Administration (FDA): Chemical Residue Monitoring of Foods Other Than Meat and Poultry

1. BACKGROUND

The Food and Drug Administration (FDA) plays three major roles in the federal effort to regulate pesticide and other chemical residues in food. The FDA:

A. Monitors levels of pesticides in foods other than meats and poultry to determine whether or not chemical residues exceed legal tolerances established by the Environmental Protection Agency (EPA);

B. Establishes tolerances for drugs administered to livestock which may leave residues in edible tissues;

C. Has the authority to prosecute when illegal amounts of pesticides and other chemicals are found during FDA's own monitoring program or during the United States Department of Agriculture's (USDA) surveillance of chemical residues in meat and poultry. Jurisdiction includes the authority to remove products containing illegal, or "adulterative", residues from interstate commerce.

This chapter will explore FDA's current roles in the federal programs that are aimed at protecting the public from chemically contaminated food.

2. FOOD AND DRUG ADMINISTRATION SURVEILLANCE SYSTEM FOR CHEMICAL RESIDUES IN FOODS OTHER THAN MEAT AND POULTRY

Donald Kennedy, Commissioner of the Food and Drug Administration, testified before the Subcommittee on February 24, 1978, about FDA's roles in the federal effort to regulate toxic substances in edible commodities. Dr. Kennedy described his conception of an ideal monitoring system for chemical residues in food in his opening statement to the Subcommittee:

> As we [at FDA] see it, any residue surveillance system contains seven elements:
> 1. A statistically valid program of food sampling that tracks usage and prevalence.
> 2. An analytical ability to detect residues accurately and rapidly.
> 3. An ability to follow up and remove violative products.
> 4. The ability to amend or revoke tolerances without cumbersome administrative procedures.
> 5. A set of regulatory sanctions that deter repeated violations.
> 6. An intelligence system that provides early warnings about potential problems or changes in use patterns, production practices, or consumption habits, and criminal prosecutions, and is thus unable to successfully deter repeated violations.
> 7. Adequate toxicological data on each chemical before it is approved, including an adequate analytical method." [91]

[91] *Hearings*, supra note 8, p. 256.

Dr. Kennedy then added:

> As you will see from the account that follows, in a number of respects, the system that the Food and Drug Administration has in place is not adequate." [92]

During its investigation and hearings, the Subcommittee found that Food and Drug Administration programs and procedures seriously lacking in all seven areas FDA Commissioner Kennedy cited as essential elements of a chemical residue monitoring system. Specificially:

1. No "valid program of food sampling that tracks usage and prevalence" exists. FDA's so-called "market basket survey", which analyzes a "typical total diet" for chemical residues, is not statistically valid and is not based on knowledge of pesticide and animal drug usage.
2. Many toxic substances known to occur in food lack adequate detection methods and are therefore not monitored by the FDA.
3. FDA infrequently removes violative products from the market.
4. Tolerances are very rarely revoked.
5. FDA has no authority to mete out civil penalties to those responsible for violations of chemical residue tolerances in meat and poultry, is reluctant to initiate.
6. No central source keeps track of changes in toxic chemical usage, agricultural practices, consumption habits, etc.
7. Tolerances have been granted (by EPA and FDA) for many chemicals that lack adequate toxicological data.

A. FDA Residue Monitoring Program

The Food and Drug Administration is responsible for monitoring raw agricultural commodities other than meat and poultry for residues of pesticides that have been approved for use by the Environmental Protection Agency (from 1970 to the present) or by FDA itself (prior to 1970). FDA's monitoring program is aimed at determining whether chemical residues remaining on mature produce are within the legal limits (tolerances) established by either EPA or FDA.

FDA also monitors "action levels", legal limits for chemicals which cannot be lawfully used on food or animal feed crops, but are present in the environment and therefore show up as residues in food. Action levels are usually established by the EPA at FDA's request when high levels of non-tolerance chemicals appear in food.

In its 1975 review of FDA's monitoring program for chemical residues in food the General Accounting Office turned up serious inadequacies in the scope of FDA's chemical monitoring. GAO recommended that FDA expand its surveillance program to include pesticide residues which were not being monitored. However, on February 14, 1978, Henry Eschwege, Director of the Community and Economic Development Division of the GAO, told the Subcommittee that its 1977 follow-up review, performed at the Subcommittee's request, showed that:

> FDA did not concur with our [GAO's] recommendation to expand its surveillance program because FDA believed that over a period of years the results of its existing program had indicated that pesticide levels found in most agricultural commodities are generally well below established tolerances—violative levels of pesticides were found in only about 3 percent of the samples tested.[93]

However, Mr. Eschwege reported that GAO had reached a conflicting conclusion:

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[92] *Ibid.*
[93] *Ibid.*, p. 8.

We [at GAO] concluded that the 3 percent rate of violative samples FDA noted indicated that illegal residues do occur despite efforts to the contrary. This occurrence demonstrated to us a need for FDA to initiate a systematic procedure to insure that all pesticides with tolerances are tested in FDA's surveillance program over a number of years.[94]

268 pesticides had legal tolerances for residues in raw agricultural commodities at the time of Subcommittee hearings. However, Mr. Eschwege told the Subcommittee that FDA's most commonly used "multi-residue" test only detects 73 chemicals. According to Mr. Eschwege, "FDA has five additional multi-residue methods which would enable FDA to detect 34 additional pesticides, or a total of 107 of the 268 pesticides. However, FDA was unable to provide [GAO with] data on how many times the additional multi-residue methods were used." [95]

5,984 tolerances exist for the 271 pesticides now registered for agricultural use.[96] (A separate tolerance is established for each crop on which a particular chemical is used.) 940 of the 5,984 tolerances are for chemicals which are suspected of causing cancer or other tumors. 661 (70 percent) of these tolerances are for suspect carcinogenic pesticides not detected by FDA's most commonly used multi-residue method.

Detection methods exist for many pesticides which remain as residues on crops, but are not routinely monitored by the FDA. Mr. Eschwege told the Subcommittee:

Methodologies do exist for detecting residues of pesticides having tolerances. However, most of these methods are single residue methods that detect only one pesticide per analysis, Public exposure to the many pesticides detectable only by single residue methods is largely unknown because FDA has rarely used these methods.[97]

Therefore, toxic pesticides, including many that are suspect carcinogens, are applied to the food we eat, but the federal regulatory agency with the duty to protect the public from such chemicals by preventing adulterated foods from entering commerce, the FDA, not only fails to prevent exposure, but does not even monitor for most toxic pesticide residues.

When FDA uncovers a residue violation, it has the authority to remove affected produce from the market. Unfortunately, violations are rarely found in time for FDA seizure and most contaminated produce is sold to the public. During hearings on February 24, 1978, Commissioner Kennedy told the Subcommittee:

By the time we have completed our analysis of a product and found an illegal residue, it is often very difficult for us to do more because the product has already been distributed in the marketplace.[98]

However, Commissioner Kennedy told the Subcommittee, "The picture isn't entirely bleak," pointing out that:

Most state health or agricultural departments have administrative detention authority which enables them to hold products. We can, by working with state officials, sometimes prevent distribution of suspect products until the analytical work is completed.[99]

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[94] *Id.*
[95] *Id.*
[96] As of September 1978.
[97] *Ibid.*, p. 8.
[98] *Ibid.*, p. 258.
[99] *Id.*

Expanding on the issue of state involvement in chemical residue monitoring programs, Commissioner Kennedy said:

I think it is important to note that there are very significant monitoring activities at the state level, particularly in highly progressive, very forward-looking states like California.

These states collect, together, many more samples than we do, perhaps ten times as many in the aggregate. California alone, in fact, collects more than the Food and Drug Administration does.

We have, ourselves, provided exchanges of results and regulatory information with state officials. We've provided training methods, manuals, advice on analytical methodology . . . , and analytical reference standard materials in an attempt to build those state programs.

They give us, in turn, inspectional and analytical information.[100]

However, the Subcommittee learned that reciprocity between state officials and the FDA is, in fact, extremely limited. Only 6 states (Maryland, Virginia, Pennsylvania, Delaware, Iowa and Oregon) have entered into agreements with the FDA which, according to Commissioner Kennedy, "provide for them to investigate illegal residues reported by USDA to determine their cause and to develop the background for whatever regulatory action is warranted." [101]

Later, under questioning from Congressman Marc L. Marks (R-Pa.), Commissioner Kennedy said, "probably we're going to find that the states with whom we have agreements are those that have active programs." If that is the case, the Subcommittee is forced to conclude that FDA-state residue monitoring reciprocity is far more limited than necessary to provide an adequate reciprocity program.

B. "Market Basket" program

In testimony before the Subcommittee, Food and Drug Administration Commissioner Kennedy described an adjunct FDA residue monitoring program, instituted in 1975, which is known as the "total diet" or "market basket" survey. The survey, which is conducted annually, is based on thirty market basket samples purchased in retail stores in various regions of the country. Twenty market baskets contain foods eaten by adults and ten are designed to represent the diets of infants and toddlers. Commissioner Kennedy explained the nature and purpose of the program to the Subcommittee:

A sample represents the entire 14-day diet—in the case of the adult sample, approximately 117 food items of a typical 18-year-old American male in the region of collection.

The foods are prepared as for the table, divided into a dozen food class composites, and then each composite is analyzed for residue content. These are used to determine which food classes contribute the greatest residues to the diet and to pinpoint seasonal and regional trends.[102]

The "total diet" survey is riddled with weaknesses, beginning with the following shortcomings brought to the Subcommittee's attention by Commissioner Kennedy himself in the following statement:

I [Mr. Kennedy] think that a major deficiency in these programs is the general absence of intelligence on actual pesticide usage, production practices, and changes in food consumption patterns.[103]

Commissioner Kennedy further indicated that FDA often does not have enough information on the pesticides used on each market basket

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[100] *Ibid.*, p. 258.
[101] *Ibid*, p. 308.
[102] *Ibid*, p. 257.
[103] *Id.*

item. This makes it difficult for FDA to know which pesticides are present and need to be analyzed. He also agreed with the statement that FDA may not find what it is seeking because it is not studying all the possible compounds. Therefore, even though the compound may be present, it may not appear in FDA's analyses.

Chairman Moss expressed concern about the practice of using the typical diet of a teenaged male as an exclusive representation of adult consumption habits, asking Commissioner Kennedy:

> Isn't there a difference in the diet characteristics of the American male and the American female? And are we not interested in what the effect might be on the female? [104]

Commissioner Kennedy replied to the Moss query:

> I would certainly think we should be, Mr. Chairman.[105]

In fact, a Library of Congress report addressing the issue of consumption patterns in the U.S., submitted for the February 14th hearing record, points out that consumption habits do vary according to such basic factors as age, sex, region of the country, and food preference. FDA's market basket survey ignores these variations in eating habits, taking into account only dietary discrepancies for infants and, in a statistically meaningless fashion, region of the country. Thirty "market baskets" cannot possibly represent valid geographic eating patterns for the entire United States.

In a letter submitted to the Subcommittee by the General Accounting Office, GAO's Henry Eschwege offered additional criticisms of FDA's market basket or total diet study:

> . . . although the total diet study does test for some heavy metals, it uses the same multi-residue detection methods as FDA's pesticide surveillance program and, therefore, it will provide information on the same pesticides detected in the surveillance program. As we have previously noted, only up to 107 of the 268 pesticides for which tolerances have been set will be detected if all six FDA multi-residue methods are used. In addition, the total diet study is an information gathering program which does not serve as a basis for regulatory action. [106]

The GAO letter also stated:

> . . . a dozen or more foods are blended together in slurries which are then analyzed for residues; violative pesticide residues in a particular food product could often escape detection.[107]

While the "market basket" program does provide FDA with some useful information about chemical residues in food, the subcommittee concludes that its deficiencies render it useless as a statistical or regulatory tool.

3. FDA FOLLOW-UP OF USDA MONITORING PROGRAM

The Food and Drug Administration is responsible for investigating violations uncovered during United States Department of Agriculture (USDA) monitoring for chemical residues in meat and poultry. FDA has the authority to mete out criminal penalites to growers who ship chemically violative animals to slaughter. It also has the responsibility to remove "adulterated" produce (containing above-tolerance levels of chemical residues) from the market.

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[104] *Ibid*, p. 281.
[105] *Id.*
[106] Letter from Henry Eschwege, GAO, addressed to Richard Heller, Counsel, subcommittee on Oversight and Investigations dated Feb. 24, 1978.
[107] *Ibid.*

Between the years 1973 and 1976, USDA reported 3,100 meat and poultry chemical residue violations to the FDA. However, the Food and Drug Administration only investigated 37 percent of the violation cases. From 1975 to 1977, FDA recalled no poultry and prosecuted no violative growers identified by USDA residue monitors.

According to General Accounting Office testimony:

> FDA generally issues information letters to growers even if the violation was caused by the grower's deliberate misuse of drugs.[108]

There are several reasons for FDA reticence concerning prosecution of violating growers. According to GAO testimony:

> USDA's monitoring program is not designed to enable FDA to develop the case histories needed to support stronger regulatory actions [than issuance of letters]. FDA officials told us [GAO] that FDA generally will not prosecute a grower for the first violation. Because animals sampled under the monitoring program are randomly selected it is unlikely that a grower will be sampled frequently enough to enable FDA to develop a case history.[109]

Since FDA has no authority to hand out civil penalties, it appears reluctant to impose a criminal penalty on a one time violator of a pesticide or drug residue law. If FDA were given the ability to administer civil penalties (fines) it can reasonably be assumed that it would not be as reluctant to enforce the law against violators.

Seizures of meat and poultry are rare because, by the time a residue violation has been uncovered during USDA monitoring, it is too late to stop sale of the contaminated produce. And because meat and poultry are often not identifiable once they have been shipped to market, federal recall of violative produce is doubly difficult.

Finally, concerning FDA's lack of aggressiveness in investigating residue violations reported to it by the USDA, Commissioner Kennedy told the Subcommittee:

> Our experience has shown us that when analytical results are given to us after a certain period of time has elapsed after the sample was taken, that the probability that the follow-up will yield anything is extremely low.
>
> I think what our people have been doing is to adopt a strategy of pursuing only those violations that constitute a warm trail.[110]

Lack of inter-agency program coordination is a serious problem in the regulatory effort to control chemical residues in meat and poultry. Both Commissioner Kennedy of the FDA and Assistant Secretary for Food and Consumer Services of the USDA, Carol Tucker Foreman, recognized this and expressed the need for greater FDA–USDA program coordination during testimony before the Subcommittee.

4. SUBCOMMITTEE FINDINGS AND CONCLUSIONS

The Food and Drug Administration is failing to carry out its statutorily mandated programs to control harmful chemical residues in food in a manner that provides the American public with adequate protection. FDA is charged with the responsibility of monitoring the country's food supply (other than meat and poultry) for chemical residues FDA's monitoring programs are seriously inadequate.

The Food and Drug Administration also has the duty to remove contaminated food from the marketplace. This it is rarely able to do.

More specifically, the Subcommittee finds specifically that:

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[108] *Hearings*, *supra* note 8, p. 100.
[109] *Ibid.*, p. 115–116.
[110] *Ibid.*, p. 281.

1. 271 pesticides are approved for use in agriculture and may potentially remain as chemical residues in food. Only 73 of these pesticides are detected by FDA's commonly used "multi-residue" detection method. While five other multi-residue tests are able to detect an additional 34 pesticides, FDA was unable to document the extent to which these methods were used. Many other pesticides may be detected in food through the use of "single residue" detection methods. However, FDA refuses to use single residue tests in its regular monitoring programs. An alarming number of pesticides are considered carcinogens or suspect carcinogens. The Food and Drug Administration only regularly monitors 30 percent of these chemicals.

2. FDA is rarely able to remove contaminated meat from the marketplace before it is sold because residue detection tests used by the FDA in its chemical monitoring programs take longer to perform than these products take to move through the marketing process.

3. Analysis of products contained in FDA's "total diet" or "market basket" survey, which tests thirty "market baskets" of food purchased in various regions of the country annually, is not based on knowledge of pesticide usage and production patterns and is therefore only marginally valuable. The survey is designed to test for chemical residues in typical diets of adults, infants and toddlers. However, all twenty "adult" market baskets are based on a typical diet for a teen-aged male, ignoring proven dietary differences attributable to such factors as age, sex, and geographic location.

4. Although FDA Commissioner Kennedy testified that the coordinated efforts of state health and agricultural officials and the FDA substantially increase the effectiveness of FDA's residue monitoring, the Subcommittee finds that state and FDA reciprocity is, in fact, quite limited.

5. The United States Department of Agriculture reported 3,100 residue violations to the Food and Drug Administration for follow-up investigation from 1973 to 1976. FDA only investigated 37 percent of these cases and few culminated in regulatory action. Because FDA has the authority to impose criminal, but not civil, penalties on growers who send violative animals to slaughter, it is reluctant to prosecute one-time residue violators.

6. FDA sets tolerances for drugs administered to livestock. For Subcommittee findings and conclusions regarding animal drugs, see Chapter Two, page 5.

5. SUBCOMMITTEE RECOMMENDATIONS FOR IMPROVING FOOD AND DRUG ADMINISTRATION REGULATORY PROGRAMS CONCERNING CHEMICAL RESIDUES IN FOOD

A. The Subcommittee recommends that Congress:

1. Consider legislation which would provide the Food and Drug Administration with authority to impose civil penalties on growers who send contaminated animals to slaughter.

2. Provide FDA with the necessary personnel and funds to improve its monitoring programs.

B. The Subcommittee recommends that FDA:

1. Substantially increase its surveillance program for chemical residues in food. Chemical detection methods should be improved

to (a) include more substances, and (b) require less time to perform. FDA should use all detection methods available to it, including selective use of "single residue" testing where no alternatives exist, to provide the public with improved protection from dangerous levels of harmful chemicals in food.

2. Base its chemical monitoring program on greater knowledge of pesticide and animal drug usage. Knowledge of where and how potentially carcinogenic chemicals are used is especially critical to an effective monitoring program. Whenever violative levels of substances suspecting of causing birth defects or mutations are found special intensive monitoring should be commenced. Every effort should be made to stop the sale of contaminated food.

3. Improve and expand its "market basket" survey. Changes in the survey should include:

(*a*) increased knowledge of the chemicals used on each product collected;

(*b*) analyzing for a larger rate of chemical contaminants;

(*c*) controlling for differences in consumption patterns. The survey should control for sex, age, and regional food preferences.

4. The FDA should continue its efforts to interest states in reciprocal agreements involving agricultural chemical monitoring being careful not to withdraw any of its own energies as state programs improve.

Chapter V—General Conclusion

The Subcommittee on Oversight and Investigations concludes that the federal programs designed to protect the American public from toxic chemicals in food, which are administered jointly by the United States Department of Agriculture (USDA), the Enyironmental Protection Agency (EPA), and the Food and Drug Administration (FDA), are ineffective. In some cases, existing laws need amending. (Recommendations for new legislation are presented at the close of the three chapters on agency programs.) However, in many more instances, the EPA, FDA and USDA are failing to carry out the vital responsibilities invested in them to protect the public from dangerous chemical residues in food. These failures are briefly summarized here:

EPA: The federal chemical residue monitoring system hinges on a strong pesticide tolerance setting program. However, the Environmental Protection Agency's system for setting tolerances (safe, legal limits of chemical residues that may be found in specific foods) is outdated, ineffectual, and showing few signs of improvement, EPA's Office of Pesticide Programs is veering away from the health-oriented language of the Federal Food, Drug, and Cosmetic Act, which administers the tolerance setting program, toward the "risk-benefit" balancing language of the Federal Insecticide, Fungicide and Rodenticide Act, under which pesticides are registered for use. In so doing, the EPA is putting the public at greater risk. Many tolerances remain in effect for pesticides that are known to be suspect carcinogens. Scores of other tolerances are for chemicals that have never been tested for carcinogenicity or other equally serious effects.

USDA: The United States Department of Agriculture, which is responsible for monitoring meat and poultry for residues of chemicals such as pesticides and animal drugs, is doing a poor job of finding residue violations and of preventing (in conjunction with the Food and Drug Administration) the marketing of contaminated meat. The Department's two residue monitoring programs (on the farm and in the slaughterhouse) are seriously ineffective. The "in slaughterhouse" monitoring program tests few animals and doesn't look for many harmful chemicals known to occur in meat and poultry. The "pretest" program, which enjoins growers suspected of marketing violative livestock to submit tissue samples for laboratory analysis, is easily avoided by farmers. Consequently, much of the meat and poultry consumed in this country may be contaminated. The USDA inspection stamp goes on all produce that has passed inspection for *visible* signs of health and cleanliness. The stamp is no guarantee that meat is free of chemical contaminants.

FDA: The Food and Drug Administration's role in the regulation of toxic substances in food includes monitoring agricultural produce (other than meat and poultry) for residues of pesticides and environmental contaminants, investigating and prosecuting cases of residue

violations in meat and poultry reported to FDA by USDA, and sharing responsibility, with USDA, for keeping contaminated produce out of interstate commerce. FDA's chemical monitoring program has dangerous shortcomings. Many chemicals occurring in food that are known to be suspect carcinogens or may potentially cause birth defects and genetic mutations are not monitored. FDA investigates few of the residue violations reported to it by USDA and rarely prosecutes violators. Combined USDA-FDA programs to remove contaminated meat from the marketplace almost never result in meat or poultry recalls.

Specific Subcommittee recommendations are detailed at the close of chapters 2, 3, and 4. General summaries of recommendations to the three agencies are as follows:

EPA should overhaul its tolerance setting program. Existing pesticide tolerances should be reassessed. Those lacking safety test and residue data should be revoked unless registrants produce required data before January of 1981.

Tolerances for substances suspected of causing cancer, reproductive problems, birth defects and genetic mutations should be revoked. no later than July of 1981. EPA should discontinue its practice of issuing "interim tolerances" for pesticides which have not been proven safe, or which are suspected of being safety hazards immediately.

Tolerance exemptions that have been granted over the years should be reassessed. Many tolerance-exempt pesticide ingredients are suspect carcinogens. The practice of exempting all "inert" ingredients from the tolerance-setting requirement should be curtailed by January of 1980 since some inerts are more highly toxic than active pesticides.

Tolerance-setting methodology should be brought up to date with current scientific knowledge. EPA's method of computing the "Food Factor" should be based on demographic information about food consumption.

EPA should develop a system for pesticide safety testing which removes testing from the manufacturers' own labs and places it in the hands of independent, impartial laboratores. Such a system could include Federal licensing of independent laboratories and Federal monitoring of these laboratories to assure objectivity.

Positions devoted entirely to reassessment and overhaul of the pesticide tolerance setting system should be created and filled within EPA's Office of Pesticide Programs.

USDA should allocate additional resources and personnel to its chemical residue monitoring programs. Rapid test procedures for chemicals known to occur as residues in meat and poultry should be developed on a high priority basis. The percentage of animals randomly tested for chemical residues in slaughterhouses should be increased, and where "multi-residue" test methods do not exist, USDA should use "single-residue" methods selectively.

A national identification system for livestock should be developed so that growers will not be able to evade USDA's "pretest" chemical residue monitoring program.

FDA should expand its residue monitoring program (for foods other than meat and poultry) substantially. Chemical detection methods should be improved to include more substances and require less time to perform. Where "multi-residue" tests are lacking, "single-residue" methods should be used on a selective basis.

Chemical residue monitoring should be based on a knowledge of where particular residues are likely to occur. Residue violation findings should be backed up by strong efforts to remove contaminated produce from the market.

FDA should improve its "market basket" survey, based on knowledge of consumption habits and chemical usage.

FDA should continue its efforts to integrate state-federal chemical monitoring efforts.

In addition to presenting specific agency recommendations at the close of chapters 2, 3, and 4, the Subcommittee also recommends that the U.S. Congress take action to improve the federal system for monitoring toxic pesticides in food. Recommendations to Congress are summarized here as follows:

Congress should consider passing legislation making it unlawful to use potentially carcinogenic, teratogenic[111] or mutagenic[112] pesticides on agricultural commodities, unless such substances degrade and leave no harmful metabolites in food.

Congress should consider livestock quarantine legislation, giving the United States Department of Agriculture the authority to detain from slaughter all animals suspected of containing violative chemical residues, pending laboratory test results.

Congress should give the Food and Drug Administration the authority to impose civil penalties on growers who send livestock contaminated with residues of animal drugs or pesticides to slaughter.

Overall, the Subcommittee recommends that all three agencies responsible for protecting the public against chemically contaminated food, the EPA, FDA and USDA, strive for increasingly effective programs improved research and development, greater inter-agency coordination, and a heightened awareness of the need to protect the public from unecessary exposure to harmful chemicals in food.

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[111] Teratogenic is defined as the quality of a substance to induce birth defects by acting on the embryo.
[112] Mutagenic is defined as the quality of a substance to produce permanent, hereditary genetic changes

SEPARATE VIEWS OF THE HONORABLE JAMES M. COLLINS

I have deep and serious disagreements with this report. As I read this report, the message that comes through is that what is being advocated here is a "no risk" or "Delaney" type standard with respect to pesticide regulation. Such a standard is, of course, impossible, and Congress when enacting the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) clearly recognized this fact.

Let me first say that I, of course, want to protect the public health as much or more than anyone else, but I do not believe that greatly eliminating food from the diet is the answer which is precisely what would happen if the Subcommittee Report's "no risk standard" was ever adopted. Pesticides are absolutely essential to this nation's basic food supply, but they are, after all, poison designed to kill. Chemicals powerful enough to perform this task almost by definition pose some risk. What we must do is take into account the enormous advantages of pesticides as well as their risks which is exactly the FIFRA standard and the EPA mandate.

I truly wished that we lived in a world where chemicals of this sort did not have to be used to produce a food crop, but we do not. That being the case pesticides will quite simply have to be used, but with-all possible precaution taken to preclude serious adverse effects to humans. I, thus, find the Subcommittee's report on this to be a case of well meaning though inflammatory rhetoric, but lacking in serious thought.

A case in point is the report's criticism of the EPA's Office of Pesticide Program's for balancing the requirements of the Food, Drug and Cosmetic Act (FDCA) with the requirements of FIFRA. After all does that not have to be the case, due to the fact the FIFRA recognizes that there are risks associated with the use of pesticides but that these risks must be balanced against the benefits of pesticides. An absolutist approach is simply not feasible. The Subcommittee Report views FIFRA as being somehow at odds with FDCA with FIFRA being less health oriented. I just do not see it that way. I see the two acts as complementary approaches to the same problem of how to deal with the acknowledged risks of many pesticides. I do not see one act as being more health oriented than the other.

The issue here is how best to get at the real concern of dealing with the risks. Tolerance setting is one approach and registration of pesticides is another. If registration is effective then tolerance setting will be greatly aided, but if registration is ineffective then so will tolerance setting. I, thus, believe that EPA's emphasis on registration is prudent, and more potentially efficacious. The EPA as the Subcommittee Report notes is making progress in the area of registration.

James M. Collins.

APPENDIX I

LIST OF 36 RANDOMLY SAMPLED * PESTICIDE CHEMICALS AND REQUIRED DATA NOT AVAILABLE TO SUPPORT TOLERANCES

Chemicals	Cancer or other tumors	Reproductive effects	Birth Defects	Gene Mutations
Aldrin				
Allethrin		X	X	
Atrazine			X	X
Benefin	X	X	X	X
Captan 2/				
Carbaryl 2/				
Carbophenothion			X	X
Chlordane				
2, 4-D				
Dalapon, Sodium Salt				X
DDVP 2/				
Diazinon				X
Dimethylarsinic Acid	X	X	X	X
Diuron			X	X
Endosulfan				
Endrin 1/			X	X
Ferbam		X	X	X
Guthion				X
Lanstan	X	X	X	X
Lindane 1/				
Malathion				X
Methoxychlor	X		X	X
Methyl Parathion	X			
Norea				X
Paraquat 2/				X
Parathion				
Piperonyl Butoxide 2/				X
Pyrazon				X
Pyrethrins				
Rogor				X
Ronnel			X	
Silvex		X		X
Sodium Trichloracetate	X	X	X	X
Thiodemeton	X		X	X
Thiram		X	X	X
Zineb				X
	7	7	14	23

1/ Currently undergoing RPAR review.
2/ Being considered for RPAR review.

* BY THE GENERAL ACCOUNTING OFFICE

FDA DETECTION CAPABILITIES OF PESTICIDES SUSPECTED OF CAUSING CANCER AND OTHER TUMORS

USING FDA STANDARD MULTIRESIDUE

	Chemicals				Tolerances			
		Suspected Oncogen				Suspected Oncogen		
	Total	Pre RPAR	RPAR	Total	Total	Pre RPAR	RPAR	Total
Detectable	73	3	7	10	2,240	108	171	279
Not Detectable	195	11	10	21	3,632	323	338	661
TOTAL	268	14	17	31	5,872	431	509	940

USING SIX FDA MULTIRESIDUE METHODS

	Chemicals				Tolerances			
		Suspected Oncogen				Suspected Oncogen		
	Total	Pre RPAR	RPAR	Total	Total	Pre RPAR	RPAR	Total
Detectable	107	3	8	11	3,215	108	234	342
Not Detectable	161	11	9	20	2,657	323	275	598
TOTAL	268	14	17	31	5,872	431	509	940

1/ An oncogen is a chemical which causes cancers or other types of tumors.

2/ Suspected carcinogens which are not under RPAR, are being given pre RPAR review.

Multiresidue Capabilities

There are six multiresidue pesticide detection methods which the Food and Drug Administration generally cites for use in the pesticide surveillance program. These methodologies can detect 107 of the 268 pesticides having tolerances for residues on raw agricultural commodities. The remaining 161 pesticides require single residue methodologies for enforcement of tolerances.

Method	FDA Reference	Type Pesticides Recovered	Total Number Partially or Completely recovered	Number of Known Recovered
Stardard Multiresidue/Mills, et al	PAM I 211.1;212.1	Organochlorine & Parent Organophosphate	116	7
Los Angeles/Luke et al	JAOAC 58, 1020-1026	Organochlorine, Organophosphate and Organonitrogen	32	28
Storherr	PAM I, 232.3	Organophosphorus	52	36
Holden/Carbamate	LIB 1767 b	Methylcarbamates	14	6
YIP/Chlorophenoxy Acid	JAOAC 54, 966-969	Chlorophenoxy Acids	7	5
Ramsteiner/Triazines	LIB 1874 & 1874A	Triazines	13	6

NUMBER OF FOOD SAMPLES ANALYZED WITH METHODS OTHER THAN FDA'S COMMONLY USED MULTIRESIDUE METHOD (FISCAL YEAR 1977)

1.	Mirex and HCB (milk, eggs, root crops)	144
2.	Triazines (corn, forage, friuts)	96
3.	Kepone (fish)	168
	Kepone and Mirex (fish)	132
4.	Dibromochloropropane (DBCP) and ethylene dibromide (EDB)	564[1/]
5.	Organophosphate, Organonitrogen, Organochlorine, Hydrocarbon (imported fruits and vegetables)	1,334 (approx.)
		2,438

1/ These samples were analyzed over both fiscal year 1977 and 1978.

APPENDIX II

SPECIAL PESTICIDE REVIEWS DIVISION
STATUS REPORT

April 17, 1978

RPAR's ISSUED

CHEMICAL(Class of Chemicals) and PROJECT MANAGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED	DATE OF FR PUBLICATION	COMMENT PERIOD CLOSING DATE	POST RPAR STATUS
BAAM (AMITRAZ) Jeff Kempter 755-8053	Oncogenicity in mice.	4/6/77	7/18/77	Awaiting CAG rebuttal analysis
BENOMYL Esther Saito 755-8050	Reductions in non-target species (earthworms);mutagenicity(multitest); teratogenicity in rats; reproductive effects(spermatogenic reduction in rats); hazard to wildlife (aquatic organisms).	12/6/77	3/24/78	Rebuttal package in OPP
BHC Frank Parsons 755-5851	Oncogenicity, fetotoxicity and reproductive effects in mice and rats.	10/19/76	11/19/76	Converted to Lindane products
CADMIUM Richard Troast 755-8050	Oncogenicity in humans (epidemiological data); mutagenicity (multitest); teratogenicity, fetotoxicity and metabolic effects.	10/26/77	2/10/78	Rebuttal package in OPP
CHLOROBENZILATE Joe Boyd 755-5632	Oncogenicity in mice.	5/26/76	8/30/76	TOP PRIORITY PD 2 & 3 to be combined
CHLOROFORM Alma Shea/ Anthony Inglis 755-8050	Oncogenicity in mice and rats; possible liver and kidney damage.	4/6/76	7/23/76	Supplemental RPAR being prepared
DBCP Jeff Kempter 755-8053	Oncogenicity in mice and rats; reproductive effects in test animals and possibly in humans.	9/22/77	11/7/77	Awaiting CED reviews; Final PD being drafted
DIALLATE Richard Troast 755-8050	Oncogenicity in mice and rats.	5/31/77	9/9/77	Awaiting CAG rebuttal analysis

RPAR's ISSUED cont.

CHEMICAL(Class of Chemicals) and PROJECT MANAGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED	DATE OF FR PUBLICATION	COMMENT PERIOD CLOSING DATE	POST RPAR STATUS
DIMETHOATE Bill Waugh 755-5851	Oncogenicity in rats; mutagenicity in bacteria, yeast, fungi and mice; fetotoxicity and reproductive effects in mice.	9/12/77	1/6/78	Awaiting CAG rebuttal analysis
EBDC's Nancy Beach 755-8050	Oncogenicity in mice and rats; Teratogenicity in rats; hazard to wildlife(aquatic organisms).	8/10/77	12/23/77	Awaiting CAG rebuttal analysis
ENDRIN Kyle Barbehenn 755-8050	Oncogenicity in rats; teratogenicity in hamsters,reductions in endangered species(Brown Pelican and Bald Eagle); Reductions in non-target aquatic species.	7/27/76	11/4/76	TOP PRIORITY Awaiting CAG rebuttal analysis
ETHYLENE DIBROMIDE Anthony Inglis 755-8053	Oncogenicity in rats; mutagenicity (multitest); reproductive effects (bulls, mice, rats and chickens)	12/14/77	4/3/78	Rebuttal package in OPP
ETHYLENE OXIDE Joe Boyd 755-5632	Mutagenicity (multitest); testicular atrophy in laboratory rats and guinea pigs.	1/27/78	5/15/78	Rebuttal period
KEPONE Fred Hageman 755-5851	Oncogenicity in mice and rats.	3/25/76	6/10/76	RPAR process completed
LINDANE Fred Hageman/ Roger Britting-ham 755-5851	Oncogenicity, fetotoxicity and reproductive effects in mice and rats; Acuts toxicity in aquatic and avian species	2/17/77	6/20/77	TOP PRIORITY Awaiting reports from CAG and CED

RPAR's ISSUED cont.

CHEMICAL(Class of Chemicals) and PROJECT MANAGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED	DATE OF FR PUBLICATION	COMMENT PERIOD CLOSING DATE	POST RPAR STATUS
MALEIC HYDRAZIDE Bipin Gandhi 755-8050	Oncogenicity in mice, mutagenicity in plants, flies,rats; reproductive effects in rats.	10/28/77	2/13/78	Rebuttal package in OPP
PCNB Jeff Kempter 755-8053	Oncogenicity in mice	10/13/77	2/6/78	Awaiting CAG rebuttal analysis
PRONAMIDE Richard Troast 755-8050	Oncogenicity in rats .	5/20/77	8/29/77	Awaiting CAG rebuttal analysis
STRYCHNINE/ STRYCHNINE SULFATE Bill Coniglio 755-5632	Reductions in non-target avian populations; fatalities in endangered species.	12/1/76	3/7/77	TOP PRIORITY PD 2 & 3 to be combined
1080/1081 Bill Coniglio 755-5632	Fatalities in non-target mammalian species and endangered species.	12/1/76	3/7/77	TOP PRIORITY PD 2 & 3 to be combined
2,4,5-T Harvey Warnick 755-5851	Possible oncogenicity and teratogenic and fetotoxic effects due to dioxin contaminants	4/21/78	6/5/78	Rebuttal period
THIOPHONATE METHYL Esther Saito 755-8050	Mutagenicity and reduction of non-target species (earthworms)	12/7/77	3/27/78	Rebuttal package in OPP
TOXAPHENE Fred Hageman/ Roger Brittingham 755-5851	Oncogenicity in mice and rats; Other chronic effects and reductions in non-target aquatic, avian and mammalian species.	5/25/77	9/13/77	Awaiting reports from CAG and CED

VOLUNTARY CANCELLATIONS

CHEMICAL (Class of Chemicals)	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED	DATE OF FR PUBLICATION
ACRYLONITRILE (three products) Rick Reising 755-7012	Possible oncogenicity, teratogenicity and neurotoxicity.	pending
ARAMITE	Oncogenicity	4/12/77
ARSENIC TRIOXIDE (some products) Bill Waugh/Anita Schmidt 755-5851	Oncogenicity, mutagenicity, and teratogenicity.	pending
BENZAC Tom Miller 755-9336	Oncogenicity due to nitrosamine contaminants.	pending
BHC (Technical Grade only)	Oncogenicity, fetotoxicity and reproductive effects in mice and rats.	10/19/76
CHLORANIL	Possible oncogen (Innes-Bionetic Study)	1/19/77
COPPER ACETOARSENITE (some products)	Carcinogenicity, mutagenicity and teratogenicity.	4/7/77 and 4/29/77
BASIC COPPER ARSENATE (all products)	Oncogenicity	4/7/77
KEPONE (products of six formulators)	Oncogenicity in mice and rats.	7/27/77
MONURON (some products)	Oncogenicity in mice and rats.	8/16/77
OMPA (Octamethylpyrophosphoramide)	Oncogenicity	5/28/76

SEVERE OCD	Severely incapacitating obsession	11\12\15
PSYCHOSIS	Non-reality based perception.	3\1\15
NATURE OF THERAPY TO ASSISTANCE (ABBREVIATED)		
1955-2021 Freq Hospitalization		
DEGREE	Occasionally in mild and rare.	4\1\11
	Watson Effects.	-
1955-2023 Total Recovery	Severely incapacitating and prone interventionally in miscoordinations;	
DECD	Occasionally in mild and rare;	10\28\11
1955-2023 Family Outlook	Severe. Non-reality and exhausting	
CHILDHOOD UNEMPLOYED	Occasionally, redirections in	11\25\14
NATURE OF THERAPY TO CHANGE (ABBREVIATED)		
1955-2030 Low Hilit.	Conservatorship	
DISEASE	Occasionally ups to utilizations	2\8\18
SYMPTOMS	Severely restricted.	8\28\15
(Two Diagnosis)	And reservedly.	
SOCIAL WITHDRAW	Occasionally, interventionally.	3\1\11
SYMPTOMS	interventions in miscoordinations. Occasionally in rare and mild;	and 8\10\11 3\25\11, 3\30\11
EMERGENCY CHRONIC	None	11\15\11
1955-2035 Hesmal Clip (Some Pass)		
10'10,-Oxytetrahydrocortisone	Schizophrenic obsessive	Benign
(Class of Chemists)	EXCEEDS WELL ON EXCEEDED	EXHIBITION
CHEMIST	40 CBR 1955.11 CRITERIA	DATE OF RX
NORMANDY CHEMICAL COURT.		

RETURNED TO REGISTRATION

LEAD ACETATE Dave Von Sumpter 755-8053	Possible oncogenicity.	Agreement reached for transfer to FDA - 4/78

PRE-RPAR REVIEW

CHEMICAL(Class of Chemicals) and PROJECT MANAGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED	PRE RPAR REVIEW STATUS
CACODYLIC ACID AND SALTS Herman Gibb 755-5632	Evidence that it degrades in the soil to inorganic arsenic which may be carcinogenic and mutagenic; one study shows that it causes spermatogenic depression and atrophic changes in seminiferous tubules.	Awaiting CAG review of Inorganic Arsenicals-PD 1 presently being drafted
CARBARYL Kyle Barbehenn 755-8050	Teratogenicity in dogs; Reductions in non-target species (bees).	PD 1 presently being drafted
CARBON TETRACHLORIDE Ed Thomas/ Anthony Inglis 755-2972	Oncogenicity in mice, hamsters, and rats; mutagenicity, teratogenicity, embryotoxicity and hepatotoxicity.	Data review underway
COAL TAR Herman Gibb 755-5632	High incidence of skin cancer in industry workers.	PD 1 will combine Coal Tar, Creosote and Coal Tar neutral oil
CREOSOTE Herman Gibb 755-5632	Incidence of cancer in humans and experimental animals.	PD 1 will combine Coal Tar, Creosote and Coal Tar neutral oil
DDVP George Bagley/ Dave Von Sumpter 755-8053	Mutagenicity; reproductive and fetotoxic effects; possible oncogenicity.	Awaiting CAG review
DEF Bipin Gandhi 755-8050	Delayed Neurotoxicity in hens.	PD 1 presently being drafted.

PRE-RPAR REVIEW cont.

CHEMICAL(Class of Chemicals) and PROJECT MANAGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED	PRE RPAR REVIEW STATUS
EPN Richard Bright 755-5851	Neurotoxicity in chickens; Delayed irreversible nerve damage; Possible irreversible eye problems in humans.	Awaiting exposure analysis from CED
ERBON(related to 2,4,5-T) Harvey Warnick 755-5851	Possible oncogenicity and teratogenic and fetotoxic effects due to dioxin contaminants	Seeking voluntary cancellations
INORGANIC ARSENICALS (includes Arsenic Acid, Arsenic Pentoxide, Arsenic Trioxide, Sodium Arsenate, Ammonium Arsenite, Sodium Pyro-arsenate, Lead Arsenate (Basic and Standard), Calcium Arsenate, Sodium Arsenite, Copper Acetoarsenite.) Bill Waugh and Anita Schmidt 755-5851	Oncogenicity in humans (epidemiological data); mutagenicity in bacteria; teratogenicity in hamsters, mice, rats and chickens.	Awaiting CAG review
MERPHOS Bipin Gandhi 755-8050	Delayed neurotoxicity in hens.	PD 1 presently being drafted
METHANEARSONATES (includes Amine Methanearsonate, Calcium Acid Meth-anearsonate,Mono-ammonium Methanearsonate (MAMA), Monosodium Methanearsonate(MSMA), Disodium Methanearsonate (DSMA). Herman Gibb 755-5632	Evidence that Methanearsonates may degrade in the soil to inorganic arsenic which may be carcinogenic and mutagenic	Awaiting CAG review of Inorganic Arsenicals-PD 1 presently being drafted

PRE-RPAR REVIEW cont.

CHEMICAL(Class of Chemicals) and PROJECT MANAGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED	PRE RPAR REVIEW STATUS
MONURON Richard Bright 755-5851	Oncogenicity in mice and rats.	PD 1 presently being drafted.
10,10'-OXYBISPHENOXARSINE Herman Gibb 755-5632	Spermatogenic depression.	Awaiting test from registrant and revised CED exposure analysis
PARAQUAT Bill Coniglio 755-5632	Acute inhalation (possible acute dermal dilute and acute wildlife-rabbits); possible teratogenicity; possible emergency treatment; possible chronic effects(lungs); possible reduced fertility; possible environmental effects(soil); data gaps (oncogenicity and mutagenicity).	PD 1 presently being drafted
PENTACHLOROPHENOL AND DERIVATIVES Daniel Cirelli 755-2972	Fetotoxicity and teratology.	Awaiting CED exposure analysis
PERTHANE Larry Chloupek 755-8053	Oncogenicity in mice; adrenal cortical atrophy in dogs fed 1000 and 5000 ppm, no data on lower levels; reproductive effects in mice at tested levels.	PD 1 presently being drafted; awaiting approval of exposure analysis

PRE-RPAR REVIEW cont.

CHEMICAL(Class of Chemcials) and PROJECT MANAGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED	PRE RPAR REVIEW STATUS
PIPERONYL BUTOXIDE Kathy Smith 755-8294	Oncogenicity in rodents.	Data collection 90% complete; papers sent to CED for validation
RONNEL(related to 2,4,5-T) Harvey Warnick 755-5851	Possible oncogenicity and teratogenic and fetotoxic effects due to dioxin contaminants	PD 1 presently being drafted
ROTENONE Nancy Beach 755-8050	Oncogenicity in rats.	Additional material to be supplied to CAG for review
SILVEX(related to 2,4,5-T) Harvey Warnick 755-5851	Possible oncogenicity and teratogenic and fetotoxic effects due to dioxin contaminants	PD 1 presently being drafted
TREFLAN Tom Miller 755-9336	Possible oncogenicity due to nitrosamine contaminants.	Awaiting CAG report
TRIALLATE Richard Troast 755-8050	Oncogenicity in rats; mutagenicity.	PD 1 presently being drafted
TRICHLOROPON George Bagley/ Dave Von Sumpter 755-8053	Possible oncogenicity in mice, teratogenicity in rats, mutagenicity in microorganisms; possible bone marrow effects.	Awaiting CAG report
2,4,5-TRICHLOROPHENOL Mary Reece 755-2972	Possible oncogenicity in rats, teratogenic and fetotoxic effects in mice, rats and hamsters due to dioxin contaminants	PD 1 draft completed

NEW CHEMICALS FOR PRE-RPAR REVIEW

CHEMICAL(Class of chemicals) and PROJECT MANAGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED
AMITROLE Anita Schmidt 755-5851	Possible carcinogen
ASBESTOS Daniel Cirelli 755-2972	Possible oncogenicity and chronic toxicity
CAPTAN/CAPTAFOL Joe Boyd 755-5632	Possible oncogenicity, mutagenicity and teratogenicity.
DACTHAL Buck Waters 755-7012	Possible HCB contamination
DAMINOZIDE Roger Brittingham 755-5851	Possible carcinogen
DICHLOROBENZENE Bipin Gandhi 755-8050	Possible carcinogen
1,3-DICHLOROPROPENE Esther Saito 755-8050	Possible mutagen
DIMILIN Richard Troast 755-8050	Possible carcinogenicity, hazard to wildlife and other chronic effects

* It is too early in the process to project decision dates accurately.

CHEMICAL (Class of Chemicals) and PROJECT MANAGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED
DINOSEB Kyle Barbehenn 755-8050	Possible teratogen and nitrosamine contamination
EPICHLOROHYDRIN Dave Von Sumpter 755-8053	Possible oncogen, mutagen; other chronic effects
ETHYLENE DIAMINE TETRA ACETIC ACID Dan Cirelli 755-2972	Possible teratogen
FOLPET Joe Boyd 755-5632	Possible teratogenic neoplastic effects
HEXACHLOROBENZENE Buck Waters 755-7012	Possible oncogen, teratogen, mutagen
8-HYDROXYQUINOLINE Larry Chloupek 755-8053	Possible oncogen, mutagen
MALEIC ANHYDRIDE Larry Chloupek 755-8053	Possible carcinogen
PERCHLOROETHYLENE Mary Reece 755-2972	Possible carcinogen

CHEMICAL(Class of Chemicals) and PROJECT MANGER	40 CFR 162.11 CRITERIA POSSIBLY MET OR EXCEEDED
PHOSPHORUS PASTE Bill Coniglio 75! 5632	Possible toxicity and lack of specific antidote
PROBE Bill Waugh 755-5051	Possible cataractogenic effects
PROPHAM/CHLOROPROPHAM Nancy Beach 755-8050	Possible carcinogen
TRIBROMOSALAN Ed Thomas 755-2972	Possible Photosensitizer and cross-sensitizer
TRICHLOROETHYLENE Mary Reece 755-2972	Possible carcinogen
ZECTRAN Homer Hall 755-2972	Possible oncogen

* RPAR stands for Rebuttable Presumption Against Registration. See Chapter Two.

APPENDIX III

EPA assumes that no more than 7.5 ounces of the following food items are consumed per person per year:

Almonds
Artichokes
Avocados
Barley
Beet Greens
Blackberries
Black-eyed Peas
Boysenberries
Blueberries
Brussel Sprouts
Buckwheat
Casaba Melons
Chicory
Coconut
Crabapples
Cranberries
Cranshaw Melons
Currants
Dates
Dewberries
Eggplant
Elderberries
Escarole
Figs
Filberts
Garlic
Gooseberries
Greens
Hominy
Honeydew Melons
Honeyballs
Hops
Horseradish
Huckleberries
Jerusalem Artichokes
Kale
Kohlrabi
Kumquats
Leeks
Loganberries
Macadamia Nuts
Mangoes
Millet
Milo
Mollasses
Mushrooms
Muskmelons
Nectarines
Okra
Papayas
Parsley
Parsnips
Passion Fruit
Pawpaws
Pecans
Peppermint
Persian Melon
Pimentos
Plums
Quinces
Radishes
Rasberries
Rutabagas
Rye
Safflower
Salsify
Shallots
Sorghum
Spearmint
Sugar Beet Tops
Summer Squash
Sunflower
Swiss Chard
Tangelos
Tangerines
Taro
Turnip Greens
Turnips
Walnuts
Watercress
Winter Squash
Youngberries

APPENDIX IV

THE INVESTIGATION AND CLASSIFICATION OF INERT INGREDIENTS IN PESTICIDE FORMULATIONS

(EXCERPTS)

Submitted to

Criteria and Evaluation Division
Office of Pesticide Programs
Environmental Protection Agency
Washington, D. C.

FINAL REPORT

SEPTEMBER 30, 1977

EPA Contract 68–01–3431

Submitted by:

POTOMAC RESEARCH, INCORPORATED
7655 Old Springhouse Road
Westgate Research Park
McLean, Virginia 22101

Toxicological Classification

As data was collected on individual compounds, the inerts were toxicologically evaluated. Following a professional review of available literature, the inerts were categorized as:

Class 1 This category of inerts contains those found to have chemical, toxicological or environmental characteristics that require immediate attention.

Class 2 Available data indicate probable cause for alarm because chemical structure is similar to a known toxicant, or a metabolic environmental pathway may result in breakdown to known toxicant, or irreversible chronic effects are known, e.g., neurotoxicity, irreversible eye damage, skin sensitization, etc. Massive fish kills or other environmental effects also triggers this category.

Class 3 Hazard data inadequate for total review where it is apparent that the use of the inert would indicate certain test requirements.

Class 4 No hazard data found or complete testing published i.e., ideal situations.

Class 5 Nature of inert does not allow chemical definitions, i.e., manure, corn, rotten eggs, etc.; however, it is reasonable to assume no hazard exists.

Class 6 Miscellaneous Class – errors in number or name; the name could not be properly identified, number incorrect, incorrect classification, etc.

Listed in Table 3 are those compounds which were assigned a Class 1 or 2 hazard classification.

TABLE 3

CLASS 1 AND 2 COMPOUNDS

EPA Accession Number	Compound Name	Hazard Class
419	Phenarsazine oxide	1
623	Dimethylamine	1
692	Hydroxylamine Sulfate	1
695	Lead	1
734	2-Imidazolidinethione	1
766	Dioxane	1
781	Saccharin	1
914	2-Ethylhexanoic acid, nickel salt of	1
83	Diethanolamine oleate	2
272	7-Hydroxy-4-methylcoumarin	2
298	1,3-Dibutyl-2-thiourea	2
308	alpha, beta-Epoxy-beta-methylhydrocinnamic acid, ethyl ester of	2
316	Dichloroanilime	2
332	Tris (2-Butoxyethyl) phosphate	2
343	1-Methyl-2-pyrrolidene	2
433	Citric acid, tris (triethylamine) salt of	2
435	Citric acid, tris (dimethylamine) salt of	2
455	Ethylenediaminetetraacetic acid, tetrakis (triethylamine) salt of	2
461	Ethylenediaminetetraacetic acid, tetrakis (diethanolamine) salt of	2
571	Triethylamine phosphate	2
595	7-(Diethylamino)-4-methylcoumarin	2
706	Diethylenetriamine	2
724	1-Amino-2-propanol nitrite	2
736	1, 3-Diethyl-2-thiourea	2
751	Lead chromate	2
752	N, N'-Dinitrosopentamethylene tetramine	2
753	Dicyanodiamide	2
777	Propylamine nitrite	2
795	Nitromethane	2
843	Nitrilotriacetic acid, tris (triethylamine) salt of	2
850	Aniline	2
882	Triethyl phosphate	2
895	Hexane	2
898	Nonylphenol, barium salt of	2
899	Toluic acid, cadimun salt of	2
941	N-Ethyltoluenesulfonamide	2
976	1, 2-Eposybutane	2
981	Alpha, alpha-Dimethylbenzyl hydroperoxide	2
983	Atropine	2

CLASS 1 AND 2 COMPOUNDS – Continued

EPA Accession Number	Compound Name	Hazard Class
1001	Maleic anhydride	2
1007	Dimethyl ether	2
1009	2, 4, 6-Trinitrophenol, sodium salt of	2
1034	2, 2' - (Ethylamino) diethanol	2
1039	Diisopropanolamine	2
1069	Acetonitrile	2
1070	1, 2, 3-Benzotriazole	2
1085	Triethylamine	2
1093	2-Nitropropane	2
1116	Triethylamine Sulfate	2
1132	3, 4-Epoxycyclohexanecarboxylic acid, (3, 4-epoxycyclohexyl) methyl ester of	2
1193	tert-Butyl peroxide	2
1210	Dibutyldithiocarbamic acid, zinc salt of	2

EXCERPTS

"INERT INGREDIENTS OF PESTICIDE FORMULATIONS" Format
(FORMAT FOR IDENTIFICATION AND TOXICOLOGICAL APPRAISAL) I

A. EPA Accession Number and Name:

000766 Dioxane

B. American Chemical Society Chemical Abstracts Service (CAS) Name and Registry Number

1,4-Dioxane
123-91-1

C. Other Names

(S): Diethylene dioxide; 1,4-Diethylene dioxide; Diethylene ether; di (Ethylene oxide); 1,4-Dioxacyclohexane; Dioxan; 1,4-Dioxan; para-Dioxan; Dioxane; para-Dioxane; Dioxyethylene ether; Glycol ethylene ether; Tetrahydro-1,4-dioxin; Tetrahydro-para-dioxin

D. Chemical Composition

C4-H8-O2
(MW) 88.10

G. Chemical and Physical Properties (1)

H. Use as an Inert - solvent, cosolvent (17)

I. Other Uses Active? Yes ( ) No (X)
Stabilizer in chlorinated solvents. Solvent for cellulose acetate, ethyl cellulose, benzyl cellulose, resins, oils, waxes and some dyes, and as a solvent for electrical, agricultural and biomedical intermediates and for adhesives, sealants, cosmetics, pharmaceuticals, rubber chemicals and surface coatings. (1)

J. Government Regulations

1. FDA - 21 CFR 121.2520 - Can be used as a component of adhesives used in packaging, transporting or holding food. (16)

2. EPA - 40 CFR 180.1001 - Exempted from a tolerance requirement when used in accordance with good agricultural practice as an inert ingredient in pesticide formulations applied to growing crops only. (17)

3. OSHA - 29 CFR 1910.1000 - U.S. Occupational Standard
Skin: 100 ppm or 360 mg/m3 on a time weighted average. (TWA) (15)

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5. DOT - 49 CFR 172.101 - Hazard class: Flammable liquid
Label required: Flammbale liquid (18)

L. Environment

M. Toxicology

1. Human effects

a. Occupational Studies - Exposure of 12 volunteers to a concentration of 1080 mg/m3 (300 ppm) 1,4-dioxane vapor in air for 15 minutes produced irritation of the eyes, nose and throat. (6) One week's exposure to 500 ppm 1,4-dioxane resulted in the death of one worker; autopsy revealed kidney, liver and brain damage. (7)

d. Poisoning Incidents and Case Studies - 5 acute deaths due to 1,4-dioxane exposure have been reported; hemorrhagic nephritis and liver necrosis were recorded at autopsy. (8)

2. Non-Human Mammalian Effects

a. Acute toxicity - The i.p. LD of 1,4-dioxane in male Sprague-Dawley rats was 5.6 g/kg. (2) The oral LD's in mice, rats and guinea pigs were 5.7, 5.2, and 3.9 g/kg respectively. (3)

c. Absorption/Excretion - In male rats given single oral doses of 10, 100 or 1000 mg/kg 14C-1,4-dioxane, excretion of unchanged 1,4-dioxane in expired air was 0.043 mg/kg (0.43%) at the lowest dose and 252 mg/kg (25%) at the highest dose. (5)

e. Subacute - In mice, rats, guinea pigs and rabbits subjected to repeated 1.5-hour exposures to 3600 mg/m3 (1000 ppm) 1,4-dioxane in air (total exposures, 78-202.5 hours), vascular congestion of the liver and degenerative changes in the renal cortex were observed. (4)

1. Carcinogenicity - 1,4-dioxane is carcinogenic in rats and guinea pigs by oral administration: it produced malignant tumors of the nasal cavity and liver in rats and tumors of the liver and gall bladder in guinea pigs. It was also active as a promoter in a two-stage skin carcinogenesis study in mice. No carcinogenic effect was observel in one inhalation study of rats." (1) See (2), (9) - (14), as cited in (1)

N. Recommendation: Class 1

Human deaths from accidental poisoning through inhalation and skin absorption of 1,4-dioxane have been reported. The cause of death appeared to be liver, kidney and brain damage. These findings have been supported by studies in rodents. More importantly, 1,4-Dioxane has been shown to be carcinogenic in mice, rats, guinea pigs by both oral and inhalation routes of administration. Consequently, the use of 1,4-Dioxane as an inert ingredient in pesticide formulations should be discontinued in all new production batches.

O. Sources used in Search

1. On Line Data Bases
   a. Toxline
   b. Medline
   c. Chemline
   d. Other

2. Major References
   a. The Merck Index
   b. NIOSH Registry of Toxic Substances
   c. Chemical Abstracts
   d. Biological Abstracts
   e. Other

P. References and Review Articles

( ) U.S. Environmental Protection Agency, Office of Pesticide Programs, Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels, U.S. G.P.O., Washington, D.C.: 1975.

( ) Chemical Rubber Publishing Co., Handbook of Chemistry and Physics, 57th Ed., Cleveland, Ohio: 1976-1977.

( ) Condensed Chemical Dictionary, 8th Ed., Van Nostrand-Rheinhold Co., New York: 1971.

( ) Merck and Co., The Merck Index, 9th Ed., Rahway, N.J.: 1976.

( ) National Institute of Occupational Safety and Health, Registry of Toxic Effects of Chemical Substances, U.S. G.P.O., Washington, D.C.: 1976.

( ) Association of American Pesticide Control Officials, Inc., Pesticide Chemical Official Compendium, Topeka, Ks.

( ) Farm Chemicals Handbook, Meister Publishing Co., Willoughby, Ohio: 1975.

( ) McCutcheons Detergents and Emulsifiers, Allured Publishing Co., Ridgewood, N.J.: 1973.

( ) U.S. Food and Drug Administration, Department of Health, Education & Welfare, GRAS Monograph Series.

(1) World Health Organization, IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man; 11, pp 247-255, Geneva, 1976.

P. References and Review Articles (cont.)

(2) Argus, M.F.; R.S. Sohal; G.M. Bryant; C. Hoch-Ligeti; J.C. Arcos, Dose-response and ultrastructural alterations in dioxane carcinogenesis, Influence of methylcholanthrene on actue toxicity, Europ. J. Cancer; 9, pp 237-243, 1973.

(3) Laug, E.P.; H.O. Calvery; H.G. Morris; and G. Woodard, The toxicology of some glycols and derivatives, J. Industr. Hyg. Toxicol.; 21, pp 173-201, 1939.

(4) Fairley, A.; E.C. Linton; A.H. Ford-Moore, The toxicity to animals of 1:4 dioxan, J. Hyg. (Lond.); 34, pp 486-501, 1934.

(5) Young, J.D. and P.J. Gehring, The dose-dependent fate of 1,4-dioxane in male rats, Toxicol. Appl. Pharmacol.; 33, p 183, 1975.

(6) Silverman, L.; H.G. Schulte; W.W. First, Further studies on sensory response to certain industrial solvent vapors, J. Industr. Hyg.; 28, pp 262-266, 1946.

(7) Johnstone, R.T., Death due to dioxane?, AMA Arch. Industr. Hlth.; 20, pp 445-447, 1959.

(8) Barber, H., Haemorrhagic nephritis and necrosis of the liver from dioxan poisoning, Guy's Hospital Rep.; 84, pp 267-280, 1934.

(9) Argus, M.F.; J.C. Arcos, and C. Hoch-Ligeti, Studies on the carcinogenic activity of protein-denaturating agents: hepatocarcinogenicity of dioxane, J. Nat. Cancer Inst.; 35, pp 949-958, 1965.

(10) Hogh-Ligeti, C. and M.F. Argus, Effect of carcinogens on the lung of guinea pigs, In: Nettesheim, P; M.G. Hanna, Jr. and J.W. Deatherage, Jr., eds, Conference on the Morphology of Experimental Respiratory Carcinogenesis, Gatlinburg, Tenn., 1970, AEC Symposium Series No. 21, Springfield, Va., National Technical Information Service, pp 267-279, 1970.

(11) Hoch-Ligeti, C.; M.F. Argus; J.C. Arcos, Induction of carcinomas in the nasal cavity of rats by dioxane, Brit. J. Cancer; 24, pp 164-167, 1970.

(12) Kociba, R.J.; S.B. McCollister; C. Park; T.R. Torkelson; P.J. Gehring, 1,4-Dioxane. I. Results of a 2-year ingestion study in rats, Toxicol. Appl. Pharmacol.; 30, pp 275-286, 1974.

(13) Torkelson, T.R.; B.K.J. Leong; R.J. Kociba; W.A. Richter; and P.J. Gehring, 1,4-Dioxane. II. Results of a 2-year inhalation study in rats, Toxicol. Appl. Pharmacol.; 30, pp 287-298, 1974.

(14) King, M.E.; A.M. Shefner; and R.R. Bates, Carcinogenesis bioassay of chlorinated dibenzodioxins and related chemicals, Environm. Hlth. Persp.; 5, pp 163-170, 1973.

(15) U.S. O.S.H.A., Code of Federal Regulations; 29, part 1910.1000, Washington, D.C.: 1976.

(16) U.S. F.D.A., Code of Federal Regulations; 21, part 121.2520, Washington, D.C.: 1976.

(17) U.S. E.P.A., Code of Federal Regulations; 40, part 180.1001, Washington, D.C.: 1976.

(18) U.S. D.O.T., Code of Federal Regulations; 49, part 172.101, Washington, D.C.: 1976.

"INERT INGREDIENTS OF PESTICIDE FORMULATIONS" Format
(FORMAT FOR IDENTIFICATION AND TOXICOLOGICAL APPRAISAL) I

A. EPA Accession Number and Name:

000419 Phenarsazine oxide

C. Other Names

(S): Phenazarsine oxide

D. Chemical Composition

(C12-H9-As-N)2-O

G. Chemical and Physical Properties - No specific information could be found on phenarsazine oxide. The information given applies to general arsenical compounds.

H. Use as an Inert

I. Other Uses Active? Yes ( ) No (X)
This substance is very similar in structure and composition to phenarsazine chloride, which is used as a war gas. (5)

---

3. OSHA - 29 CFR 1910.1000 - U.S. Occupational Standard for arsenic and arsenic compounds 0.5 mg As/m3. (4)

M. Toxicology

1. Human effects

a. Occupational Studies - Clinical reports have documented an association of chronic arsenicism with skin cancer in vineyard workers. The risk of lung cancer is clearly increased in certain smelter workers who inhale high levels of inorganic arsenic compounds. (3)

b. Epidemiology - Phenarsazine chloride is used as a war gas and in combination with tear gas. It produces a watery nasal discharge; severe pain in the nose, sinuses, chest; sneezing, coughing, nausea, vomiting, depression, weakness and sensory disturbances. (5)

c. Metabolic Effects Studies - In all cases of arsenic poisoning, it is the ion of arsenious acid, rather than the element itself which produces the toxic effects. The in vivo conversion of it to arsenite explains why all chemical forms of arsenic eventually produce the same toxic syndrome. As arsenite, the element is an active enzyme inhibition, presumably because of its attachment to sulfhydryl groups of essential proteins. (1)

d. Poisoning Incidents and Case Studies - Absorbed arsenic is excreted largely by the kidneys, but feces, skin and hair sometimes contain appreciable amounts. (1)
Inhalation TCLo: 19 mg/m3/3 minutes produced irritation, inhalation LC50: 30 gm/kg, inhalation LCLO: 54 ppm/30 minutes (all inhalation data is for phenarsazine chloride). (2)

e. Others - Trivalent organic arsenicals such as phenylarsenoxide are more potent inhibitors of certain sulfhydrylenzymes than are inorganic arsenites. (1)

2. Non-Human Mammalian Effects

a. Acute toxicity - Inhalation, LD50: rat, 14 mg/kg; guinea pig, 2.4 mg/kg; Intravenous, LD50: rabbit, 6 mg/kg (all for phenarsazine chloride) (2)

N. Recommendation: Class 1
The evidence is now overwhelming that arsenic is a carcinogen in man. Because of the ubiquitous occurrence of arsenic, contamination must be kept to a minimum consistent with the background in any particular area. Consequently, added arsenic in any form should be avoided in all pesticide formulations.

O. Sources used in Search

1. On Line Data Bases

a. Toxline
b. Medline
c. Chemline
d. Other

2. Major References

a. The Merck Index
b. NIOSH Registry of Toxic Substances
c. Chemical Abstracts
d. Biological Abstracts
e. Other

P. References and Review Articles

( ) U.S. Environmental Protection Agency, Office of Pesticide Programs, Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels, U.S. G.P.O., Washington, D.C.: 1975.

( ) Chemical Rubber Publishing Co., Handbook of Chemistry and Physics, 57th Ed., Cleveland, Ohio: 1976-1977.

( ) Condensed Chemical Dictionary, 8th Ed., Van Nostrand-Rheinhold Co., New York: 1971.

(5) Merck and Co., The Merck Index, 9th Ed., Rahway, N.J.: 1976.

(2) National Institute of Occupational Safety and Health, Registry of Toxic Effects of Chemical Substances, U.S. G.P.O., Washington, D.C.: 1976.

( ) Association of American Pesticide Control Officials, Inc., Pesticide Chemical Official Compendium, Topeka, Ks.

( ) Farm Chemicals Handbook, Meister Publishing Co., Willoughby, Ohio: 1975.

( ) McCutcheons Detergents and Emulsifiers, Allured Publishing Co., Ridgewood, N.J.: 1973.

( ) U.S. Food and Drug Administration, Department of Health, Education & Welfare, GRAS Monograph Series.

(3) World Health Organization, IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man, Geneva.

P. References and Review Articles (cont.)

(1) Gleason, M.N. et al, Clinical Toxicology of Commercial Products, Williams and Wilkins, Baltimore: 1969.

(4) U.S. O.S.H.A., Code of Federal Regulations; 29, part 1910.1000, Washington, D.C.: 1976.

"INERT INGREDIENTS OF PESTICIDE FORMULATIONS" Format
(FORMAT FOR IDENTIFICATION AND TOXICOLOGICAL APPRAISAL) I

A. EPA Accession Number and Name:

001085 Triethylamine

B. American Chemical Society Chemical Abstracts Service (CAS) Name and Registry Number

Ethanamine, N, N-diethyl-
121-44-8

C. Other Names

(T): TEN

D. Chemical Composition

$(C_2H_5)_3N$
(MW) 101.19

I. Other Uses Active? Yes ( ) No (X)
in the preparation of quaternary ammonium compounds (1)

L. Environment

1. Effect - Aquatic Toxicity Rating - TLm 96: 100-10 ppm (2)
Triethylamine was found to be produced naturally by Streptococcus lactis. (10)

M. Toxicology

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c. Metabolic Effects Studies - Short-term inhalation of triethylamine by humans disrupted central nervous system activity. (9)

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2. Non-Human Mammalian Effects

a. Acute toxicity - Oral, LD50: rat, 460 mg/kg; mouse, 546 mg/kg; Inhalation, LCLo: guinea pig or rat, 1000 ppm/4 hours; Skin, LD50: rabbit, 570 mg/kg (2)

b. Pharmacology - Short and long-term inhalation of triethylamine vapors disrupted cerebrocortical activity, porphyrin metabolism, and increased blood cholinesterase activity. (9)

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d. Metabolism - In fatal doses to rats, triethylamine was found to significantly inhibit the enzymic activity of monoamine oxidase in the liver and brain. (11)

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h. Mutagenicity - Triethylamine inhaled by rats at 1 mg/m3 for 3 months, induced an 18%-24% frequency of aneuploid cells in the bone marrow, compared with 0%-2% in controls. (8)

i. Carcinogenicity - Nitrosamines are produced when triethylamine reacts with nitrous acid. (7)

N. Recommendation: Class 2

While triethylamine in and of itself is a moderately toxic compound as an inert ingredient in pesticide formulations, use levels could be devised that would pose no hazard to animal and human health. However, under certain circumstances, triethylamine can react with nitrites to produce a highly potent carcinogen, the corresponding nitrosoamine. An example using morpholine along with nitrites in the diet with a consequent high frequency of tumor production has been the subject of several publications. The controversial addition of nitrites to bacon and sausages is another example. Because of the inherently explosive publicity that could be generated by others, it would be highly desirable for EPA to have investigations underway to determine the circumstances that could lead to nitrosoamine production from triethylamine.

O. Sources used in Search

1. On Line Data Bases
   a. Toxline
   b. Medline
   c. Chemline
   d. Other

2. Major References
   a. The Merck Index
   b. NIOSH Registry of Toxic Substances
   c. Chemical Abstracts
   d. Biological Abstracts
   e. Other

P. References and Review Articles

( ) U.S. Environmental Protection Agency, Office of Pesticide Programs, Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels. U.S. G.P.O., Washington, D.C.: 1975.

(3) Chemical Rubber Publishing Co., Handbook of Chemistry and Physics, 57th Ed., Cleveland, Ohio: 1976-1977.

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APPENDIX V

I. LIST OF PESTICIDES SUSPECTED OF CAUSING TUMORS *

	CFR Reference (Title 40)	Pesticide
1.	180.110	Maneb
2.	180.115	Zineb
3.	180.126	Inorganic bromides resulting from soil treatment with ethylene dibromide
	180.146	Inorganic bromides resulting from fumigation with ethylene dibromide
4.	180.127	Piperonyl butoxide
5.	180.175	Maleic hydrazide
6.	180.192	Calcium Arsenate
7.	180.194	Lead Arsenate
8.	180.196	Sodium Arsenate
9.	180.197	Inorganic bromides resulting from soil treatment with 1, 2-dibromo-3-chloropropane
10.	180.198	Dimethyl (2,2,2-triochloro-1-hydroxethyl) phosphonate
11.	180.204	Dimethoate including its oxygen analog
12.	180.217	Ammoniates for [ethylenebis-(dithiocarbamato)] zinc and ethylenebis [dithiocarbamic acid bimolecular cyclic anhydrosulfides and disulfides
13.	180.235	2,2 - Dichlorovinyl dimethy phosphate
14.	180.246	Daminozide
15.	180.277	S-2,3 - Dichloroallyl diisopropylthiocarbamate
16.	180.289	Methanearsonic acid
17.	180.311	Cacodylic acid
18.	180.317	3,5 - Dichloro - N - (1,1 - dimethyl-2 -propynl) benzamide
19.	180.335	Sodium arsenite

* The above list of pesticides was taken from a list that GAO gave to FDA subsequent to GAO's February 14, 1978, testimony.

SUMMARY OF FDA'S REGULATORY ACTIONS INVOLVING HUMAN AND ANIMAL FOODS

CONTAMINATED WITH PESTICIDES, HEAVY METALS, OR INDUSTRIAL CHEMICALS

+PMS Project	Seizure			Prosecution			Citation			Injunction			Recall		
	75	76	77	75	76	77	75	76	77	75	76	77	75	76	77
05 Chemical Contamination (Human Foods)	32*	5	33**	0	0	1	0	1	1	0	0	2	13	7	6
01 Animal Feed Safety	1	0	0	0	0	2	0	2	0	0	0	0	1	94***	0

* Includes 13 seizures of chlorodane contaminated potatoes involving one establishment

** Includes 26 seizures of mercury contaminated swordfish or halibut

*** Includes 60 recalls of cottonseed meal from Mississippi contaminated with pesticides (PCNB and Disyston) and mercury. Also includes 25 recalls resulting form chlorodane contaminated feed in Louisiana.

+Program Management System

2/23/78

FY 1975

SEIZURES

PMS 05 Chemical Contamination (Human Foods)

SAMPLE NO.	PRODUCT	CONTAMINANT
21-642 H	Radishes	Dacthal
10-130 H	Chubs, fresh	Dieldrin
19-517 H	Potatoes	Chlordane
59-541 H	Potatoes	Chlordane
10-131 H	Chubs, fresh	Dieldrin
10-126 H	Chubs, fresh	Dieldrin
DI 43-502 H	Dinnerware, silverplated	Lead
53-415 H	Coffee Set	Lead
19-539 H	Potatoes	Chlordane
70-366 H	Radishes	Dacthal
28-326 H	Coho Salmon, canned	Polychlorinated Biohenyls
95-082 H	Potatoes	Chlordane
91-885 H	Potatoes	Chlordane
113-614 H	Potatoes, fresh white	Chlordane
73-971 H	Wheat	Malathion
114-059 H	Coffee Beans	Sodium Aluminum Fluoride
80-983 H	Barley	Malathion
20-882 H	Salmon	Polychlorinated Biphenyls
4-697 H	Potatoes	Chlordane
10-127 H	Chubs, fresh	Dieldrin
54-581 H	Soybeans	Ronnel
69-703 H	Potatoes	Chlordane
84-534 H	Noodles	Diazinon
89-387 H	Potatoes	Chlordane
90-271 H	Potatoes	Chlordane
90-272 H	Potatoes	Chlordane
90-274 H	Potatoes	Chlordane
90-649 H	Potatoes	Chlordane
90-871 H	Potatoes	Chlordane
108-619 H	Navy Beans, Michigan	Methylbromide
109-702 H	Swordfish, frozen	Mercury
DI 115-682 H	Cheese, Feta	Hexachlorobenzene

PMS 01 - Animal Feed Safety

SAMPLE NO.	PRODUCT	CONTAMINANT
80-453 H	Veg. Oil (Ultra Fat) Veg.	Dieldrin

FY 1975

RECALLS

PMS 05 Chemical Contamination (Human Foods)

RECALL NO	PRODUCT	CONTAMINANT
F-012-5	Silverplated Baby Cups (India)	Leachable Lead
F-028-5	Stainless Steel Electric Kettle	Leachable Lead
F-029-5	Canned Evaporated Milk	Polybromated Biphynels (PBB)
F-031-5	Electric Teakettles	Leachable Lead
F-038-5	Burclock Root	Atropine
F-084-5	Silverplated Baby Cups (India)	Leachable Lead
F-090-5	Canned Fruit Cocktail	Sodium Sulfite
F-111-5	Potato Chips	Hydrocarbons
F-114-5	Soya-Lecithin Capsules	Hexane
F-132-5	Carmel Danish Rolls	Alergic Rections to Brazil Nuts Not Declared on Label
F-142-5	Corn Chips, Potato Chips, Tortilla Chips & Cheese Puffs	Alkaline Crystals
F-146-5	Sweet Cream Butter	Labeling Ink on Wrapper
F-154-5	Rice Oil	Malathian

PMS 01 Animal Feed Safety

RECALL	PRODUCT	CONTAMINANT
V-002-5	Feed Supplement Blocks	Dieldrin

FY 1976

SEIZURES

PMS 05 Chemical Contamination (Human Foods)

SAMPLE NO.	PRODUCT	CONTAMINANT
76-336 H	Fish Oil	Polychlorinated Biphenyls
76-06-700	Swordfish	Mercury
76-28-651	Lettuce	Methyl 3
76-32-993	Yellow Grease	Endrin
76-53-186	Frozen Halibut	Mercury

CITATIONS

PMS 05 Chemical Contamination (Human Foods)

PRODUCT	CONTAMINANT
Swordfish	Mercury

PMS 01 Animal Feed Safety

PRODUCT	CONTAMINANT
Cottonseed Meal (2 Citation)	PCNB, Disyston, Chloroneb & Mercury

RECALLS

PMS 05 Chemical Contaminants (Human Foods)

RECALL NO.	PRODUCT	CONTAMINANT
F-003-6	Beer	Chlorinated Phenols
F-020-6	Frozen popsicles	Calcium Chloride
F-029-6	Fresh Parsley	Parathion
F-027-6	Cocktail vegetable juice	Tin
F-069-6	Rice Pudding	Soapy Taste
F-091-6	Sharp Cheddar Cheese	Toluene
F-134-6	Vinyl Coated Aluminum Casserole Dish	Vinyl coating

FY 1976

RECALLS

PMS 01 Animal Feed Safety

RECALL NO.	PRODUCT	CONTAMINANT
V-013-6	Feed Supplement with Magnesium Oxide	Molybdenum
V-015-6	Bulk Animal Feed	Lead
V-017/021-6	60 Related Recalls of Animal	Mercury
V-022/039-6	Feeds With Cottonseed	Disyston
V-041/057-6	Meal	PCNB
V-059/073-6		Malathian
V-074/078-6		Methoxychlor
		Chloroneb
		HCB
		Captan
V-083-6	Mineral Feed Supplement	Lead and Arsenic
V-084-6	6 Related Recalls of Feed	Molybdenum
V-091/095-6	with Magnesium Oxide	
V-102/121-6	25 Related Recalls	Heptachlor
V-124/128-6	of Animal Feeds	and Trans Chlordane

FY 77

SEIZURES

PMS 05 Chemical Contaminants (Human Foods)

SAMPLE NO.	PRODUCT	CONTAMINANT
76-43-266	Swordfish	Mercury
77-43-741	Swordfish	Mercury
77-43-414	Swordfish	Mercury
77-12-577	Swordfish	Mercury
77-78-340	Swordfish	Mercury
77-78-336	Swordfish	Mercury
77-91-555	Swordfish	Mercury
77-42-670/1	Swordfish	Mercury
77-14-482	Swordfish	Mercury
77-91-278	Swordfish	Mercury
77-89-706	Swordfish	Mercury
77-59-663	Swordfish	Mercury
77-59-667	Swordfish	Mercury
77-89-506	Swordfish	Mercury
77-97-713	Mahi Mahi Fillets	Mercury
77-10-384	Halibut	Mercury
77-71-557	Halibut	Mercury
77-53-464	Halibut	Mercury
77-70-540	Halibut	Mercury
77-72-089	Halibut	Mercury
77-72-098	Halibut	Mercury
77-72-095	Halibut	Mercury
77-17-681	Halibut	Mercury
77-72-091	Halibut	Mercury
77-72-094	Halibut	Mercury
77-52-909	Halibut	Mercury
77-03-884	Halibut	Mercury
77-31-056	Wheat	Potassium Chloride
77-30-516/20	Mass Seizure	Pesticide
77-30-526/27	Multiple Foods	
77-26-382/83	Wheat	Mercury
77-49-295	Rice	Diazinon
77-50-356	Mung Beans	Endrin

PROSECUTION

PMS 05 Chemical Contaminants (Human Foods)

PRODUCT	CONTAMINANT
Swordfish	Mercury

FY 77

PROSECUTION

PMS 01 Animal Feed Safety

PRODUCT	CONTAMINANT
Cottonseed Meal (2 Prosecutions)	PCNB, Disyston Chloroneb & Mercury

CITATION

PMS 05 Chemical Contaminants (Human Foods)

PRODUCT	CONTAMINANT
Swordfish	Mercury

INJUNCTIONS

PMS 05 Chemical Contaminants (Human Foods)

PRODUCT	CONTAMINANT
Swordfish (2 Injuctions)	Mercury

RECALLS

PMS 05 Chemical Contaminants (Human Foods)

RECALL NO.	PRODUCT	CONTAMINANT
F-014-7	Grapefruit Juice, canned, sweetened	Can detinning
F-046-7	Dinners and Foods, frozen	Ammonia
F-047-7	Beer, Michelob	Inner coating (Lacquer) blistering
F-051-7	Pretzels	Sodium Hydroxide
F-125-7	7 UP Carbonated beverage	Chemical (Aliphatic Hydrocarbon and Mineral spirits)
F-133-7	Mahi Mahi Fish, Frozen	Histamine

APPENDIX VII

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

OMMUNITY AND ECONOMIC
DEVELOPMENT DIVISION

February 24, 1978

Mr. Richard A. Heller
Counsel
Subcommittee on Oversight and Investigations
Committee on Interstate and Foreign Commerce
House of Representatives

Dear Mr. Heller:

At your request we are providing information relating to conclusions in our testimony that FDA should expand its residue testing program.

Total Diet Study

We do not consider FDA's total diet study an appropriate substitute for FDA's pesticide surveillance program because a dozen or more foods are blended together in slurries which are then analyzed for residues; violative pesticide residues in a particular food product could often escape detection.

Further, although the total diet study does test for some heavy metals, it uses the same multiresidue detection methods as FDA's pesticide surveillance program and, therefore, it will provide information on the same pesticides detected in the surveillance program. As we have previously noted, only up to 107 of the 268 pesticides for which tolerances have been set will be detected if all six FDA multiresidue methods are used. In addition, the total diet study is an information gathering program and does not serve as a basis for regulatory action. FDA's Deputy Associate Commissioner for Compliance has, in the past, informed us that this program is not intended to be statistically valid or representative of the typical diet of the general population.

Tolerance Violation Rate

Our comments regarding FDA's 3 percent pesticide violation rate were based on information provided to GAO by FDA. FDA discussed this point in its letter commenting on our draft report. The letter stated:

> "Additionally, we do not believe that the recommended action is commensurate with the relative seriousness of pesticide residues in food. Each year, FDA samples about 7000-8000 shipments of food and feed for pesticide residues. As indicated in the GAO report, less than 3 percent of these shipments contain residue levels in excess of established tolerances. The incidence of pesticide residues in most raw agricultural commodities is generally of a low order and their levels are frequently well below established tolerances."

As can be seen, there is no reference that the rate of violation pertains to other than pesticide residues in excess of established tolerance levels. In discussion with FDA officials during February 1978, we were told that the rate of pesticide violations was 3.1 percent for the objective sampling program and 6.8 percent for sampling based on local intelligence.

At your request we reviewed FDA's computer printout of the approximately 6,400 domestic food samples analyzed during FY 1977. We found that FDA's various district offices reported that 198 (3.1 percent) of the approximately 6,400 samples examined were violative. Of the 198 samples, 106 (1.7 percent of the total) contained violative levels of pesticides or their metabolites or decomposition products--levels which exceeded either established tolerances or FDA administrative guidelines or action levels. Additionally, 32 of the 106 that contained violative levels of pesticides also contained violative levels of other contaminants such as mercury or PCB. The remaining 92 violative samples which did not contain reported violative levels of pesticides were violative because of heavy metal (mercury, lead, cadmium) or industrial waste (PCB, HCB) contamination.

Although the 1.7 percent pesticide violation rate is less than FDA told us originally, we still believe the rate is significant, particularly because FDA checks for only about 25 percent of the pesticides with tolerances. We continue to believe that FDA's program should be expanded so that all pesticide with tolerances are periodically sampled. It also appears appropriate that FDA sample more frequently for those pesticides suspected of causing adverse effects such as cancer or other tumors, birth defects, etc.

Methods Used by FDA in Surveillance Program

In our testimony, we stated that FDA's most used multiresidue method does not identify 20 pesticide chemicals suspected of causing cancer or other tumors. These 20 chemicals have 612 individual tolerances. Because this multiresidue method is used up to 80 percent of the time, these chemicals will not be monitored up to 80 percent of the time in FDA's pesticide surveillance program. We believe that chemicals with potential to cause cancer and other tumors should be monitored more frequently than this.

In a January 1978 letter, FDA said that it could not tell us either the number of times each multiresidue method was used in its surveillance program or the results of all of its specialized pesticide surveys conducted during FY 1977. (See pages 2 and 3 of Enclosure I.) In our testimony we cited all of the special surveys on which FDA provided us information and provided the Subcommittee a list of these special FY 1977 surveys. (See Enclosure II.)

At your request we asked FDA about its monitoring of these 20 suspect chemicals. An FDA official told us that FDA has tested or will test for residues of 12 of the 20 suspect chemicals. He said residues of seven were tested for in the total diet study which, as we have previously noted, does not form the basis for regulatory action. He said two others are detected by a method available for use in the compliance program, however, he could not tell us how many tests were performed using this method and we noted that use of the cited method was not required in the FY 1977 compliance program. He said residues of two others will be detected in the ETU special survey that was begun in FY 1977. The twelfth chemical will be tested for in an FDA special survey planned for FY 1978.

We continue to believe that it is not sufficient for FDA to place reliance in a pesticide surveillance program that tests for only 25 percent of the residues for which tolerances have been set. In a similar vein, we believe that little reliance can be placed in the total diet study to identify violative levels of pesticide on individual food commodities when up to a dozen or more foods are blended together and tested as one product.

- - - -

We trust that the foregoing satifies your needs. We will be happy, however, to provide any additional information that you may find necessary.

Sincerely yours,

Henry Eschwege

Henry Eschwege
Director

Enclosures - 2 - Not Printed

APPENDIX VIII

LIST OF ANIMAL DRUGS,
PESTICIDES, AND ENVIRONMENTAL CONTAMINANTS
WHICH MAY RESULT IN RESIDUES IN
RAW MEAT AND POULTRY

A) Included in USDA monitoring (24 out of 47 drugs and pesticides have adequate methods

- Animal drugs (3 of 26 have detection methods for regulatory purposes (m))

m 1) Arsenic

2) Carbadox

3) Chlortetracycline

4) Clopidol

5) Decoquinate

6) Dichlorvos

7) Diethylstilbestrol

8) Erythromycin

9) Ipronidazole

10) Levamisole hydrochloride

m 11) Monensin

12) Neomycin

13) Oxytetracycline

14) Penicillin

15) Robenidine hydrochloride

16) Streptomycin

17) Sulfachlorpyridazine

18) Sulfadimethoxine

19) Sulfaethoxypyridazine

20) Sulfamethazine

21) Sulfanitran

A) Included in USDA monitoring

Animal drugs

22) Sulfathiazole

23) Sulfomyxin

24) Tetracycline

25) Thiabendazole

m 26) Zeranol

Pesticides (21 of 21 have adequate methods)

m 27) Aldrin

m 28) Benzene Hexachloride

m 29) Chlordane

m 30) Coumaphos

m 31) DDT

m 32) Diazinon

m 33) Dieldrin

m 34) Dioxathion

m 35) Endrin

m 36) Ethion

m 37) Gardona

m 38) Heptachlor

m 39) Lindane

A) Included in USDA monitoring

Pesticides

m 40) Malathion

m 41) Methoxychlor

m 42) Methyl Parathion

m 43) Mirex

m 44) Parathion

m 45) Ronnel

m 46) Toxaphene

m 47) Trichlorofon

Environmental contaminants

48) Cadmium

49) Copper

50) Hexachlorobenzene

51) Iron

52) Lead

53) Mercury

54) Polybrominated biphenyls

55) Polychlorinated biphenyls

B) Not included in USDA monitoring (35 of 97 have adequate methods)

Animal drugs (3 out of 41 have adequate methods)

1) 2-Acetylamino-5-nitrothiazole
2) Alkomide
3) Ampicillin
4) Amprolium
5) Bacitracin
6) Buquinolate
7) Carbomycin
8) Cephapirin
9) Chlorhexadine
10) Chlormadinone acetate
11) Cloxacillin
12) Dihydrostreptomycin
13) Dimetridazole

B) Not included in USDA monitoring

Animal drugs

14) 3,5-Dinitrobenzamide

15) Estradiol benzoate

16) Estradiol monopalmitate

17) Ethopabate

18) Furazolidone

19) Gentamicin sulfate

20) Gentian violet

21) Haloxon

22) Hygromycin B

23) Lasalocid sodium

24) Lincomycin

25) Melengestrol acetate

26) Metoserpate hydrochloride

27) Nequinate

28) Novobiocin

29) Nystatin

30) Oleandomycin

31) Ormetoprim

32) Progesterone

33) Pyrantel tartrate

34) Reserpine

B) Not included in USDA monitoring

Animal drugs

35) Sodium sulfachloropyrazine monohydrate

36) Spectinomycin

37) Testosterone

38) Testosterone propionate

39) Tylosin

40) Virginiamycin

41) Zoalene

Pesticides (32 out of 56 have adequate methods)

m 42) Acephate

m 43) Aldicarb

m 44) Atrazine

45) Azinophosmethyl

m 46) Benomyl

m 47) sec-Butylamine

m 48) Captan

m 49) Carbaryl

m 50) Carbofuran

m 51) Carbophenothion

m 52) Chlordimeform

D) Not included in USDA monitoring

Pesticides

m 53) Chlorobenzilate

m 54) Chlorpyrifos

m 55) Crufomate

m 56) 2,4-D

m 57) Dalapon

m 58) Daminozide

59) Def

60) Demeton

m 61) Dialifor

m 62) Dimethoate

63) Diphenylamine

64) Disyston

65) Diuron

66) Dodine

m 67) Endosulfan

m 68) Fenthion

69) Ficam

70) Guthion

m 71) Hexakis

72) Linuron

73) Maneb

74) Methanearsonic acid

m 75) Methoprene

76) Naled

B) Not included in USDA monitoring

Pesticides

m 77) Paraquat

78) Pentachlorophenol

79) Perthane

m 80) Phorate

m 81) Phosolone

m 82) Piperonyl butoxide

83) Plictran

84) Polyram

85) Propachlor

m 86) Propargite

m 87) Pyrethrins

88) Sencor

m 89) Silvex

m 90) Simazine

91) Stam

m 92) 2,4, 5-T

93) Terbacil

m 94) TDE

95) Tetradifon

96) Zinc ion and maneb coordination product

97) Zineb

* Provided to the Subcommittee by the General Accounting Office.

APPENDIX IX

VIOLATION RATES, AS DETECTED BY USDA

Table 1 *

Species	Violation rate
Cattle	14.96
Calves	8.84
Sheep and Goats	2.60
Swine	15.83
Horses	6.71
Chickens	5.08
Turkeys	8.46
Ducks and Geese	12.51
Rabbits	6.64

* Provided to the Subcommittee by the General Accounting Office. Years included are 1974, 1975, 1976.

Table 2

Pesticides	Samples Analyzed	Samples Violative	Percent Violativ
Chlorinated hydrocarbons a/	13534	232	1.71
Organophosphates	800	3	.38
Animal drugs			
Antibiotics	12420	436	3.51
Arsenic	6986	69	.99
Diethylstilbestrol	7502	47	.63
Zeranol	249	0	
Zearolinone	250	0	
Sulfas	8016	300	3.74
Clopidol	382	0	0.00
Monensin	910	1	0.11
Carbadox	2148	13	0.61
Thiabedazole	149	0	0.00
Levamisole	4	0	0.00
Decoquinate	97	0	0.00
Robenadine	763	9	1.18
Ipronidazole	820	17	2.07
Environmental contaminants			
Mercury, cadmium, lead, copper	2414	34	1.41
Iron	178	0	0.00
PBB	39	0	0.00
	57,661	1161	

a/ Includes the environmental contaminants polychlorined biphenyls and hexachlorophene.

APPENDIX X

ANIMAL DRUGS AND PESTICIDES SUSPECTED OF CAUSING CANCER OR BIRTH DEFECTS

I Cancer

A) Animal drugs included in USDA monitoring

m 1) Arsenic

2) Carbadox

3) Diethylstilbestrol

4) Ipronidazole

5) Sulfamethazine

6) Sulfathiazole

B) Animal drugs not included in USDA monitoring

7) Chlormadinone acetate

8) Dimetridazole

9) Estradiol benzoate

10) Estradiol monopalmitate

11) Furazolidone

12) Gentian violet (not an approved animal drug but reported as being used.)

13) Melengestrol acetate

14) Progesterone

15) Testosterone

C) Pesticides included in USDA monitoring

m 1) Aldrin

m 2) Benzene hexachloride

m 3) Chlordane

m 4) DDT

m 5) Dieldrin

m 6) Endrin

m 7) Heptachlor

m 8) Lindane

m 9) Mirex

m 10) Ronnel

m 11) Toxaphene

m 12) Trichlorofon

D) Pesticides not included in USDA monitoring

m 13) Captan

m 14) Carbaryl

m 15) Chlorobenzilate

m 16) Dimethoate

17) Maneb

18) Perthane

m 19) Piperonylbutoxide

20) Polyram

m 21) Silvex

m 22) 2,4-5-T

m 23) TDE

24) Zinc ion and maneb coordination product.

25) Zineb

II Birth Defects

A) Animal drugs included in the monitoring program

None

B) Animal drugs not included in the monitoring program

1) Chlormadinone acetate

2) Reserpine

C) Pesticides included in the monitoring program

m 1) Ronnel (based on dioxin contaminant)

m 2) Endrin

m 3) Trichlorofon

D) Pesticides not included in the monitoring program

m 1) Captan

m 2) Carbaryl

m 3) 2,4-D

4) Demeton

5) Diphenylamine

m 6) Fenthion

7) Maneb

m 8) Paraquat

9) Pentachlorophenol (photodegrades to dioxin)

m 10) Silvex (based on dioxin contaminant)

m 11) 2,4,5-T (based on dioxin contaminant)

12) Zineb

m 13) Benomyl

APPENDIX XI

Glossary of Terms

CPSC—Consumer Product Safety Commission
EPA—Environmental Protection Agency
FDA—Food and Drug Administration
GAO—General Accounting Office
NIOSH—National Institute of Occupation Safety and Health
OSHA—Occupational Safety and Health Administration
USDA—U.S. Department of Agriculture
FFDCA—Federal Food, Drug, and Cosmetic Act
FIFRA—Federal Insecticide, Fungicide and Rodenticide Act

Toxic=
Acute toxicity: adverse effects from a single dose. Mortality in 50 percent of the animals exposed
Subacute Toxicity: adverse effects from repeated exposure over a short period of time, usually 90 days
Oncogenicity: power of a substance to incite tumor formation, either benign or malignant in living tissue
ability to induce tumors
Teratogenicity: ability of a substance to induce birth defects by acting on the embryo
Teratogenic: quality of a substance to induce birth defects by acting on the embryo
Mutagenic: quality of substance to produce permanent, hereditary genetic changes
Mutagenicity: power of a substance to produce permanent, hereditary genetic changes. Genetic mutations may not be apparent for generations
Chronic feeding-oncogenicity: chronic feeding over most of test animals' lifetimes to determine whether substance induces growth of tumors
Reproduction: testing to determine whether a substance causes adverse effects on animals' abilities to reproduce: size and health of offspring, effects on fertility
Teratogenicity: testing to determine whether a substance causes birth defects
Mutagenicity: testing to determine whether substance causes genetic changes that will be passed on to future generations
Pesticides: pest killers
herbicides: weed killers
fungicides: mold, mushroom, mildew, and rust destroyers and repellants
insecticides: insect killers

USDA Programs:

Random Sample Monitoring Program: analyzes tissue samples from a percentage of randomly selected animal carcasses in slaughterhouses

Pretest Program: enjoins growers who have shipped animals with above-tolerance levels of pesticides or animal drugs to market in the past, to provide the department with laboratory analyses of livestock samples prior to slaughter

Hold and test

Surveillance

Adultered: chemically contaminated

Carcinogens: cancer causers

Inert: substance does not have active pesticide properties

Suspect carcinogens: See Inert definition above

Violative: containing illegal levels of chemical residues (meat products, animals)

Market Basket Survey: analyzes typical total diet

Pesticide tolerances for raw agricultural commodities: maximum amounts of active pesticide ingredients that may be legally present in or on particular foods and animal feeds. EPA establishes under terms of FFDCA.

Action levels:

Legal limits for chemicals which cannot be lawfully used on food or animal feed crops, but are present in the environment and therefore show up as residues in food.

Legal amounts of chemical residues that may be present in foods for which no tolerances have been established.

Established tolerance: maximum amount of a chemical that may be legally present in a particular commodity.

Residue: amount of a pesticide remaining in or on food following normal product use.

Potential exposure:

Total potential daily exposure: based on all tolerances that have been set for that pesticide and an average daily diet estimate for an American male.

Acceptable daily exposure: level of total potential daily exposure below which exposure considered safe.

Permissible exposure is calculated from the following information:

(1) NOEL—No Observable Effect Level

Level of a substance administered to a group of experimental animals at which those adverse effects observed or measured at higher levels are absent.

Rats or mice are usual test animals.

NOEL expressed in parts per million (ppm) and converted to milligrams per kilogram of body weight per day (mg/kg/day).

(2) Safety Factor or "Factor of 100"

Rationale for using 100. Man appears to be 10 times as sensitive to toxic substances as the rat and sickness increases the susceptibility of man to such substance 10 times.

(3) ADI: Acceptable Daily Intake

$$\text{ADI} = \frac{\text{NOEL}}{\text{Safety Factor}}$$

(4) MPI: Maximum Permissible Intake
MPI=ADI×Average weight of an adult (i.e., Average wt. of an adult=60 kg=132 lbs.).
TMRC: Theoretical Maximum Residue Contribution
Maximum potential exposure
TMRC=Proposed tolerance×Food factor×Daily diet.
Food Factor: Estimate of how much of the commodity to be treated with the pesticide will be eaten daily by the average American (based on average consumption for the total population).
Daily Diet: 1500 grams (3.3 pounds).

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UNIVERSITY OF FLORIDA
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